

AD-A254 299



ATION PAGE

Form Approved
OMB No. 0704-0188

Agency should not respond, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information, sending comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Avenue, Washington, DC 20540, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE May 1992	3. REPORT TYPE AND DATES COVERED THESIS/ DISSERTATION 1
4. TITLE AND SUBTITLE Effect of Head Insulation on the Total Time Required to Rewarm Postoperative Cardiac Surgery Patients		5. FUNDING NUMBERS
6. AUTHOR(S) Michelle Ann Ryerson, Captain		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AFIT Student Attending: University of Texas		8. PERFORMING ORGANIZATION REPORT NUMBER AFIT/CI/CIA- 92-044
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) AFIT/CI Wright-Patterson AFB OH 45433-6583		10. SPONSORING / MONITORING AGENCY REPORT NUMBER
11. SUPPLEMENTARY NOTES		
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release IAW 190-1 Distributed Unlimited ERNEST A. HAYGOOD, Captain, USAF Executive Officer		12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

DTIC
S **ELECTE** **D**
A
AUG 24 1992

92 8 21 130

92-23457

14. SUBJECT TERMS		15. NUMBER OF PAGES 100	
		16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

**EFFECT OF HEAD INSULATION ON THE TOTAL TIME REQUIRED TO
REWARM POSTOPERATIVE CARDIAC SURGERY PATIENTS**

**A
THESIS**

**Presented to the Faculty of
The University of Texas Graduate School of Biomedical Sciences
at San Antonio
in Partial Fulfillment
of the Requirements
for the Degree of
MASTER OF SCIENCE IN NURSING**

**By
Michelle Ann Ryerson, B.S.**

San Antonio, Texas

May, 1992


DTIC QUALITY INSPECTED 8

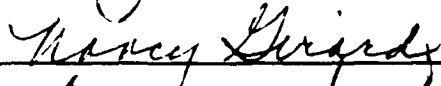
Accession For	
NTIS CRA&I	<input checked="checked" type="checkbox"/>
DTIC TAB	<input type="checkbox"/>
Unannounced	<input type="checkbox"/>
Justification	
By	
Distribution/	
Availability Codes	
Dist	Avail and/or Special
A-1	

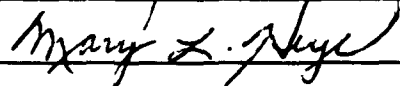
EFFECT OF HEAD INSULATION ON THE TOTAL TIME REQUIRED TO REWARM
POSTOPERATIVE CARDIAC SURGERY PATIENTS

Michelle A. Ryerson

APPROVED:



Supervising Professor




4/28/92
Date:

APPROVED:



Sanford A. Miller, Ph.D.
Dean

ACKNOWLEDGEMENTS

I would like to extend my sincere appreciation to the United States Air Force Nurse Corps for giving me the opportunity to attend graduate school at The University of Texas Health Science Center at San Antonio.

My deepest gratitude goes to Don Johnson, Ph.D., Mary Heye, Ph.D., and Nancy Girard, M.S.N. for their encouragement and advisement throughout this study. Special thanks also goes to Mary Lou Noll, Ph.D. for her assistance during the early phases of development and approval of the study proposal. In addition, I would like to thank the following individuals: Sondra Perdue, Ph.D. for consultation in statistical planning and analysis; Judith Shockley, M.S.N. for her assistance with data entry and processing; and Jo Ann Crow, Ph.D. for her expert consultation in preparation for the defense of this thesis.

Financial support for this endeavor was provided by: the United States Air Force Institute of Technology, the Delta Alpha Chapter of Sigma Theta Tau International, and the San Antonio Chapter of the Association of Operating Room Nurses. O.R. Concepts, Roanoke, Texas donated the Thermadrape caps and sheets used during the study. The generosity of these organizations in support of nursing research is truly appreciated.

Finally, I wish to convey my deepest regard and gratitude

to the following individuals who enthusiastically facilitated this research endeavor: Maj John Meyers, M.D., Chief of Cardiothoracic Surgery (Wilford Hall USAF Medical Center) and his staff, the perfusionists, and the nursing personnel in the operating room and the cardiothoracic surgical intensive care unit, and Col John Cissik and his staff at the Clinical Investigation Directorate, Wilford Hall USAF Medical Center, San Antonio, Texas.

EFFECT OF HEAD INSULATION ON THE TOTAL TIME REQUIRED TO
REWARM POSTOPERATIVE CARDIAC SURGERY PATIENTS

Publication No. _____

Michelle Ann Ryerson, MSN

The University of Texas Graduate School of Biomedical Sciences
at San Antonio

Supervising Professors: Don Johnson, R.N., Ph.D.
Mary Heye, R.N., Ph.D.
Nancy Girard, R.N., M.S.N.

The purpose of this study was to was to examine the
relationship between head insulation and the length of time
required to rewarm postoperative cardiac surgery patients when

it is employed as an adjunct to conventional methods used to restore body heat after induced hypothermia. Physiological researchers revealed the absence of vasoconstrictor reflexes in the head and demonstrated significant heat loss from this area of the body (Froese & Burton, 1957; Hertzman & Roth, 1942; Shvartz, 1970). Three investigators (Biddle & Biddle, 1985; Morgester, 1987) demonstrated clinically and statistically significant decreases in heat loss during the intraoperative and postoperative periods with use of head insulation. Other investigators (Erickson & Yount, 1991; Howell et al., 1992) reported no beneficial effect from head insulation for abdominal or cardiac surgery patients during the perioperative or postoperative period. Urinary bladder temperatures of 33 male and 3 female patients between the ages of 42 and 75 years old undergoing coronary artery bypass graft surgery were recorded at 5 specific intervals in the operating room (OR) and in the cardiothoracic surgical intensive care unit (CTSICU) of a large military hospital in South Central Texas. The patients were randomly assigned to an experimental group and a control group. Group I (N = 19) wore aluminized polyethylene caps from the start of the rewarming period on cardiopulmonary bypass until their temperatures reached 36.5°C in the CTSICU. Group II (N = 17) wore paper caps in the OR (infection control policy) and no head cover in the CTSICU. Contrary to what was expected, based on previous studies that

examined the effect of head insulation, a two-tailed t-test revealed no significant difference between the groups for mean total rewarming time ($p = .650$) or the rate of change in the urinary bladder temperature during the rewarming period ($p = .442$). Clinically, it is significant that head insulation, in this particular sample population, did not appear to influence the amount rewarming time or the rate at which the subjects rewarmed.

There may be subpopulations of cardiopulmonary bypass patients (not identified in this study due to the small sample size and exclusion criteria) who might benefit from head insulation during rewarming, for example, patients who are over 75 years of age or patients with extreme baldness. Additionally, high risk patients, such as those experiencing non-surgical blood loss, patients who experienced lower levels of induced hypothermia on cardiopulmonary bypass, or patients with known problems with wound healing may benefit from any measures that could protect them from further sources of inadvertent heat loss. Since postoperative hypothermia can cause serious complications for cardiac surgery patients, nurses must continue to investigate different techniques for improving the efficiency of their rewarming efforts.

TABLE OF CONTENTS

	Page
Title	i
Approval	ii
Acknowledgements	iii
Abstract	v
Table of Contents	viii
List of Tables	xi
List of Figures	xii
 I. INTRODUCTION	 1
A. Problem Overview/Need for Study	1
B. Problem Statement	4
C. Purpose of Study	4
D. Hypothesis	4
E. Definition of Terms	4
F. Assumptions	6
 II. REVIEW OF THE LITERATURE	 7
A. Theoretical Framework	7
1. Thermoregulation	7
2. Induced hypothermia	8
3. Physiological principles of heat loss	9
4. Rewarming	10
B. Review of the Literature	11
1. Heat loss from the head	11
a. Physiological experiments on	

heat loss from the head	12
b. Intraoperative head insulation	15
c. Perioperative head insulation	17
d. Postoperative head insulation	18
2. Temperature monitoring site	21
3. Drugs that may affect thermoregulation	27
a. Anesthetic agents	27
b. Morphine	29
c. Nitroglycerine and nitroprusside	30
4. Physiological effects of rewarming	31
a. Shivering	32
5. Age and rewarming	33
6. Rewarming methods	34
a. A rewarming strategy	37
7. Summary	39
III. Methods	42
A. Design	43
1. Control of extraneous variables	44
B. Population and Sample	45
C. Procedures	46
1. Setting	46
2. Randomization of sample	46
3. Data collection procedure	47
a. Criteria for discontinuing study	49
D. Instrumentation	50

E.	Data Analysis	51
F.	Limitations	52
1.	Threats to Internal and External Validity .	53
G.	Ethical Considerations and Protection of Subjects	53
IV.	RESULTS	56
A.	Overview	56
B.	Hypothesis Testing	65
V.	DISCUSSION OF RESULTS	68
A.	Discussion	68
1.	Total rewarming time	70
2.	Total temperature change	70
3.	Rate of change in urinary bladder temperature	71
4.	Challenges of clinical research	75
B.	Applications to Nursing Practice	76
C.	Recommendations for Future Research	78
VI.	APPENDICES	82
A.	Appendix A (Authorizations)	82
B.	Appendix B (Consent Form)	85
C.	Appendix C (Data Collection Tool)	89
VII.	REFERENCES	95
VIII.	VITA	100

LIST OF TABLES

	Page
Table 1 Preoperative Data (Demographic and Other) on Subjects in Groups I and II	59
Table 2 Preoperative Medical/Surgical History of Subjects	60
Table 3 Perioperative Rewarming Data on Group I (Experimental)	61
Table 4 Perioperative Rewarming Data on Group II (Control)	62
Table 5 Percentage of Subjects in Each Group that Received Specific Drugs During the Perioperative Period	63
Table 6 Means, Medians, Standard Deviations, and Ranges for Groups I and II on Rewarming Measurements	66
Table 7 Difference in Rewarming Variables with T-tests	67

LIST OF FIGURES

	Page
Figure . Pretest-posttest Design Used for Study	43

CHAPTER I

Introduction

Problem Overview/Need for Study

Body temperature is a measure of the balance between heat loss and production. The human body jealously guards its internal temperature. The demands of temperature regulation take first place even over the demands of other homeostatic mechanisms (Flacke & Flacke, 1983, p. 183). Consequently, shivering or vasodilation will occur in the hypovolemic patient, or in one with compromised cardiac function, even to the point of cardiovascular collapse in an effort to maintain temperature balance (Flacke & Flacke, 1983, p. 183).

General anesthesia and deep hypothermia interrupt the hypothalamic regulation of temperature balance causing extreme heat losses. In addition to general anesthesia, induced hypothermia is used during cardiac surgery to decrease metabolic oxygen demands, create a bloodless operative field, and reduce the amount of required anesthesia (Earp, 1989). Physiological hazards associated with hypothermia include: decreased enzymatic efficiency (associated with acid-base balance and clotting abnormalities), cardiovascular depression, a left shift of the oxyhemoglobin dissociation curve, arrhythmias, oliguria, imbalance in organ demand for oxygen and its supply, decreased cerebral blood flow, and alteration in drug disposition (Biddle & Biddle, 1985).

The systemic hypothermic state induced during cardiac surgery is a readily identified nursing problem. During postoperative rewarming, peripheral vasodilation is frequently accompanied by acute hypotensive, hypovolemic episodes. In addition to hemodynamic changes, the body's compensatory response to hypothermia is shivering. The efficiency of heat generation by shivering has been documented as just 11% (Earp, 1989). The metabolic demands of shivering can increase oxygen consumption 300 to 800 percent above resting levels (Earp, 1989), accelerate the production and accumulation of lactic acid, and result in metabolic acidosis (Lennon, Hosking, Conover, & Perkins, 1990). Shivering can be life-threatening in postoperative patients who already have compromised cardiac function. Consequences of hypothermia induced during cardiac surgery can include: longer intubation times, the use of vasoactive and anti-arrhythmic drugs, and blood product and fluid volume administration. Severe hypothermia can also result in serious dysrhythmias including ventricular fibrillation. The potential outcomes for cardiac surgical patients include increased mortality or prolonged intensive care and hospital stays and increased costs. Therefore, the goal of nursing intervention for this problem during the immediate postoperative period should be to rewarm these patients in a timely, efficient manner.

Efficient rewarming of hypothermic patients can be

enhanced by a basic understanding of the laws that govern body heat loss: conduction, the exchange of heat by direct contact; convection, the transfer of heat by circulation; radiation, the transfer of heat from the body to the air in the form of rays; and evaporation, the conversion of liquid by body heat into vapor. The major sources of heat loss during the rewarming period include evaporation (while the chest is open), convection, and radiation.

Rewarming is initiated in the operating room, while the patient is still on cardio-pulmonary bypass. Patients are usually rewarmed to a core temperature in the mildly hypothermic range of 34° to 37°C (Phillips & Skov, 1988). The rewarming period continues in the intensive care unit postoperatively. At this time, heat loss should be controlled to guarantee the efficiency of conventional methods of rewarming which include: various types of warming blankets (electric, water-filled, gel-filled, and forced-air), heating lamps, and warmed cotton blankets. Covering the patient's head may be one mechanism to reduce heat loss during rewarming, since documented heat loss from the human head can be as high as 25 to 60 percent of the total body heat loss (Froese & Burton, 1957). However, it has been this author's experience that insulative head coverings are not widely used. There is a need to determine whether or not head insulation should be instituted as an adjunct to conventional therapy to

prevent convective and radiant heat loss during the rewarming period for cardiac surgery patients.

Problem Statement

Does head insulation affect the total length of time required to rewarm cardiac surgery patients?

Purpose of Study

The purpose of this study is to examine the relationship between head insulation and the length of time required to rewarm postoperative cardiac surgery patients when it is employed as an adjunct to conventional medical and nursing interventions used to restore body heat after induced hypothermia.

Hypothesis

Hypothermic postoperative cardiac surgery patients wearing head covers will require less total rewarming time to reach a urinary bladder temperature of 36.5°C (97.7°F) than hypothermic postoperative cardiac surgery patients not wearing head covers.

Definition of Terms

Core

The inner organs of the human body such as the heart, liver, or brain; primary site of heat production (Phillips & Skov, 1988).

Shell

The skin, skeletal muscles, and subcutaneous tissue of

the body; insulator between core and environment (Phillips & Skov, 1988).

Hypothermic

Core body temperature less than 36.5°C (97.7°F) as measured in the urinary bladder with a thermistor-tipped foley catheter.

Postoperative Cardiac Surgery Patient

Adult patients between the ages of 21 and 75 years old who are taken to the intensive care unit immediately following coronary artery bypass graft surgery.

Head Cover

Thermadrape (aluminized polyethylene cloth) cap worn on head from moment when heat exchanger on cardiopulmonary bypass machine is set to restore heat to the patient's body in the operating room until the patient's urinary bladder temperature reaches 36.5°C in the cardio-thoracic surgical intensive care unit (CTSICU) postoperatively.

Total Rewarming Time

The total length of time (T) required for the patient's urinary bladder temperature to reach 36.5°C (97.7°F) postoperatively as the result of rewarming. Measured from the time when the heat exchanger is turned on to restore heat to the patient's body in the operating room (T_1) until the time (T_2) when the patient's UBT reaches 36.5°C (97.7°F) in the CTSICU.

Total Rewarming Time: $T = T_2 - T_1$

Assumptions

1. Patients have no preexisting undiagnosed diseases that would disrupt thermoregulatory function.
2. Blood supply to the head increases as the thermal gradient between the core and the shell increases during cold stress.
3. Heat loss from the head is a large percentage of the total body heat loss.
4. Urinary bladder temperature reflects core temperature in patients without renal disease.

CHAPTER II

Theoretical Framework and Review of the Literature

Theoretical Framework

The theoretical framework for the study was based on the physiological principles of thermoregulation and heat loss.

Thermoregulation

The temperature regulating system of the human body contains three parts: the afferent receptors, the hypothalamus, and the autonomic effector mechanisms. The afferent cold and warm receptors bring in necessary information to the temperature control center in the hypothalamus. The hypothalamus has a normal set-point temperature of approximately 37°C which may vary slightly between individuals and can be altered by such things as drugs, infection, or trauma. Under the direction of the hypothalamus, the autonomic nervous system effects necessary changes in the body temperature through heat generation (shivering), dissipation (vasodilation of peripheral blood vessels), or heat conservation (vasoconstriction of blood vessels).

Heat transfer occurs in the body between two major compartments: the core and the shell. The heart and brain are part of the core which is principally composed of viscera and is the primary site of heat production (Soukup, 1988). Thermal gradients exist within the core because different

organs have different metabolic rates and blood flow. The shell is an insulator between the core and the environment made up of skin and subcutaneous fat (Phillips & Skov, 1988). Local resistance to heat flow depends on the amount of subcutaneous fat and the vasoconstrictive ability of the underlying tissue.

Induced hypothermia

During induced hypothermia for cardiac surgery, the heart and brain are cooled first and the periphery (skin, muscle, and rectum) follows by convective transfer to the cold blood (Phillips & Skov, 1988, p. 513). Before the patient is taken off the bypass machine, heat is restored to the core, and the periphery lags behind, reestablishing the normal thermal gradient. The heart and brain are warmed first because they receive a larger percent of the cardiac output. The other parts of the core and the shell lag behind, establishing an internal thermal gradient. Blood circulating through the periphery cools and then re-cools the core on its return, producing an afterdrop of the core temperature of as much as 2°C to 5°C over a 60 to 90 minute period postoperatively (Phillips & Skov, 1988). During cold stress, blood is shunted away from peripheral body parts and the head receives increasing quantities of blood (Biddle & Biddle, 1985). Resistance to heat flow in the body depends on the amount of subcutaneous fat and vasoconstrictor capacity of the

underlying tissue (Bullard, 1970). Since the head lacks both of these characteristics (Hertzman & Roth, 1942), heat dissipates more rapidly from the head than from any other quantitatively similar body surface when exposed to cold (Shvartz, 1970).

Physiologic principles of heat loss

Heat loss from the body to a cooler external environment occurs via radiation, convection, conduction, and evaporation. Convective heat transfer between the body and the environment occurs when air flows across the skin. Convective losses are determined by the rate of air flow over the skin, body surface exposure, and the cutaneous blood flow. Exposure to the cold environment of the operating room and intensive care unit causes peripheral vasoconstriction and shunting of rewarmed core blood to an uncovered head. When the head is covered, convective heat transfer to the environment by air movement is reduced. Radiation is the loss of heat in the form of electromagnetic energy from the body to colder objects in the room. Radiation accounts for 65 per cent of the body's heat loss and may also be prevented by skin covering (Lilly, 1987). Conduction is the mechanism of heat transfer between the cells and the capillaries to the surfaces that the body touches. Evaporation is the conversion of liquid by body heat into vapor. Low humidity, high environmental temperatures, and high air current velocity increase evaporative losses

(Holtzclaw, 1986, p. 293). Conduction and evaporation contribute minimally to heat loss in the hypothermic patient unless the skin or its coverings are wet (Bligh, 1985). During coronary bypass surgery, evaporative heat loss can be substantial until the chest cavity is closed. After the chest is closed, radiation and convection account for about 80 per cent of all heat loss (Lilly, 1987, p. 101). Remarkably, as much as 50 to 60 per cent of the body's heat may be lost as radiation from the scalp because scalp blood vessels are unable to vasoconstrict (Biddle & Biddle, 1985; Lilly, 1987).

Rewarming

Rewarming cardiac surgery patients depends on restoring the balance between heat gain and heat loss. Despite the addition of heat to the body core by heat exchangers in the oxygenator post-bypass surgery, many patients arrive in the intensive care unit with subnormal temperatures. Their heat generating abilities including muscular contraction and metabolic production are inhibited by anesthetic drug effects and compromised cardiac function. Antithermoregulatory drugs, exposure and irrigation of body cavities, blood loss, infusion of cold intravenous fluids and blood products, increased cerebral blood flow, radiation, convection, conduction, evaporation, and cold ambient temperatures contribute to continued heat loss. By protecting the head, blood may retain heat and be forced to carry it to more peripheral areas of the

body.

Review of the literature

Hypothermia is induced during cardiac surgery to reduce the metabolic and oxygen demands of the tissues. Blair (1964) claimed that each 1°C drop in body temperature corresponds to a clinically significant ten per cent decrease in metabolic demand. Burns and Bostek (1990) reported factors associated with intraoperative heat loss in anesthetized surgical patients. They cited: ambient temperatures; anesthesia technique (general versus regional); length of surgery; dry, unheated anesthetic gases; cold intravenous infusions; exposure; wet skin, dressings, or linens; age extremes; anesthetic agents; and adjunct drugs and preoperative medications as possible contributors to inadvertent hypothermia.

Heat loss from the head

Despite physiologic research that revealed significant heat loss from the human head during cold stress (Froese & Burton, 1957; Hertzman & Roth, 1942; Shvartz, 1970), only a few nursing studies have investigated head insulation as a method to prevent heat loss during the perioperative and immediate postoperative period in adult patients (Biddle & Biddle, 1985; Morgester, 1987; Erickson & Yount, 1991; Howell, R. D., MacRae, L. D., Sanjines, S., Burke, J., & DeStefano, P., 1992). Only one study has been done to determine the

utility of head insulation as an adjunct to conventional rewarming methods for postoperative cardiac surgery patients (Howell et al., 1992).

Physiological experiments on heat loss from the head.

Hertzman and Roth (1942) used plethysmography to study vasoreactivity of the forehead skin of a human male subject. A photoelectric technique was used to record volume pulses while the subject slept, rested, and awakened. Attempts to elicit vasoconstrictor reflexes by startling the subject with unexpected loud noises, exposure to ice water, and deep breathing were unnoticed in the forehead area while vasoconstriction occurred simultaneously in the finger.

To test the response of forehead skin to the local application of cold, they used a plaster of paris cast of the subject's cranium and suspended the cold applicator and plethysmograph from it. Cold was simultaneously applied to the subject's finger and forehead skin. The vasomotor response of the forehead skin was slow (20 minutes) compared to the instantaneous response noted in the finger. Complete cessation of the volume pulse was never achieved in the forehead skin. The authors claimed that it was difficult to cool the forehead below 21°C because of the thermal capacity of the cold applicator. However, since hypothermia is seldom induced to temperatures lower than 21°C for cardiac surgery, the finding that vasoconstrictor reflexes are relatively

absent in the forehead skin at this temperature level has clinical implications for the study proposed.

Another physiological experiment was performed by Froese and Burton in 1957 to examine nonevaporative heat loss from the human head. Based on observations that the skin temperature of the human head remains relatively constant despite decreases in ambient temperatures, they hypothesized that cerebral vasomotor responses to cold are limited. In the laboratory, heat loss from the head was studied with the aid of a temperature gradient calorimeter. The calorimeter was calibrated prior to use. All possible sources of error considered, the largest total error was estimated at eight percent. Three human subjects were studied in two series of experiments. Each subject sat on a chair during the experiment with the calorimeter lowered over his head for 30 to 45 minutes and skin temperatures were recorded with a skin temperature bridge to the nearest 0.1°C . The breath was carried outside the calorimeter so that only the vapor losses from the skin entered the chamber. In the first series of experiments, using a repeated measures design, the physiologists recorded skin temperatures at nine different room temperatures between plus 28°C and minus 20°C . In the second series, repeated measures were carried out at three different room temperatures: one experiment on each subject, unclothed, at 10°C ; one experiment on each, clothed, at 20°C ;

and two more experiments on two of the subjects, clothed, with a heating pad on their chests at 24°C. Temperatures of the room, calorimeter, cheek, rectum, and finger were monitored. The analysis of the first series of experiments demonstrated that tissue insulation of the head was independent of the calorimeter temperature. In the second experimental series, vasoconstriction of the finger was showed to change by a factor of six times, while that of the head remains constant.

Overall, the study appears valid, controlling for all possible extraneous variables. There may be clinical significance in their finding that the total heat loss from the head at minus 4°C under experimental conditions amounted to about 50 percent of the resting heat production (Froese & Burton, 1957, p. 239). The authors proposed that a steady state (heat balance) might be realized by leaving the head unprotected and increasing the insulation of the body. However, they added that the level of additional clothing required is impractical and the same results can be achieved more efficiently through head insulation.

Shvartz (1970) conducted a related experiment on the effect of a cooling hood on physiological responses to work in a hot environment. Using six physically active, healthy subjects, ages 20 to 23 years old, he observed physiological changes to working at 50°C, 20% relative humidity, and 5 km/hr. The subjects were randomized to the following experimental

conditions: no cooling; wearing a cooling hood; and wearing the hood and a suit covering the torso, arms, and thighs. Heart rate, rectal temperature (probe inserted four inches into the rectum), oral temperature, and skin temperatures (upper arm, chest, thigh, and lower leg) were recorded every ten minutes. Analysis of the results showed that the combination of the hood and the suit was the most effective method of reducing physiological strain. There may be relevance to clinical practice because Shvartz determined that the hood alone was the most efficient method of the three in reducing heart rate (metabolic demand) based on body surface area measurements.

Intraoperative head insulation. Biddle and Biddle (1985) used these physiological findings as a framework for their investigation into the use of a plastic head cover to reduce heat loss in the elderly in the operating room. They collected data on 127 elderly subjects (65 to 90 years) undergoing major abdominal surgery of at least 75 minutes duration. No preoperative medication was administered, all patients were afebrile and without nasopharyngeal pathology. Intravenous fluids were infused at the ambient room temperature of 70°F. Temperatures were recorded at ten minutes after anesthesia induction and endotracheal intubation and 60 to 70 minutes into the perioperative period with a B-D Basal nasopharyngeal thermometer (no information as to the

reliability and validity of the instrument was included in the article). Patients in the study were randomly assigned to one of three groups: group I (N = 43) wore no head covering, group II (N = 42) wore paper surgical caps, and group III (N = 42) wore a plastic bag that covered the head and face (placed on the subjects 5 minutes after endotracheal intubation and removed before they regained consciousness). The patients were also divided into two cohort groups, Cohort A (N = 75, 65 to 77 years) and Cohort B (N = 52, 78 to 90 years).

A negative correlation was discovered between age and initial temperature ($r = -.71$) (Biddle & Biddle, 1985, p. 40). In addition, based on a "strength of association" test (q^2), the older cohort group experienced statistically significant greater heat loss in each head covering situation ($p < .005$, $q^2 = .68$) (Biddle & Biddle, 1985, p. 40). It is clinically significant that the patients who wore paper caps experienced almost the same amount of mean heat loss as the patients who had no head covering (0.90°F versus 0.95°F and 1.04°F versus 1.10°F , respectively for the two cohort groups). The subjects wearing plastic bags had the least amount of mean heat loss (0.25 to 0.30°F for the two cohort groups) (Biddle & Biddle, 1985, p. 40). The authors noted that they could not attribute any differences in the findings to sex or body build. However, one weakness noted in the methodology was that the determination of body build was very subjective and not based

on any anthropometric measurements. The authors did not report the gender ratios of the cohort groups detracting from the validity of the conclusions that were drawn about the role of sex as an extraneous variable in this particular study. There is clinical significance in that the use of a simple, inexpensive head covering conserves heat by the following mechanisms: conductive insulation by air immobilization, reduction of radiation intensities, and prevention of fast evaporative cooling (minimal effect) (Biddle & Biddle, 1985).

Perioperative head insulation. Erickson and Yount (1991) also evaluated head insulation as a strategy to minimize perioperative heat loss in patients having abdominal surgery. Using covers made of aluminized polyethylene, they compared their usefulness in three different combinations: head cover, body cover, and both to a control condition. They used infrared thermometers to measure tympanic temperatures as an indicator of core temperature (manufacturer specified accuracy $\pm 0.1^{\circ}\text{C}$). The experimental treatment was applied from the time of transport to the operating room until the patient left the post anesthesia care unit (PACU). They found that the head cover had no beneficial effect, either alone or in combination with body covers. This was an unexpected finding and the authors suggest that it may have been due to chance or an undetected interaction effect. It is important to note that none of the mean tympanic temperatures fell below 36.5°C .

Coronary bypass surgery patients undergo induced hypothermia to core temperatures generally less than 30°C. The effect of head covers in this patient population who is at special risk for body heat loss warrants investigation. In regard to the proposed study, there was another clinically useful finding in the Erickson and Yount study. After statistically controlling for potentially confounding variables of: pretransport temperature, age, body mass index, surgery time, and being covered with a warmed blanket on operating room admission, a one-way analysis of covariance revealed a statistically significant difference between the groups ($F = 5.241$, $p < .01$) (Erickson & Yount, 1991). PACU entry temperatures were higher in patients with aluminized body covers.

Postoperative head insulation. In a similar study, Morgester (1987) sought examine head insulation as a means of facilitating rewarming of the adult postoperative patient in the recovery room. Using a quasi-experimental design, rectal temperatures of 46 male postoperative patients (ages 60 to 78 years) were recorded for the first two-hour period in the recovery room. Individuals were excluded from the study if they had cardiac surgery, craniotomies, surgeries precluding the use of rectal probes postoperatively, coagulation defects, or preoperative hyperthermia. There was no mention of exclusion for a history of peripheral vascular disease which can alter thermoregulatory function. Control and experimental

groups, including subdivisions for anesthesia method, were established by random assignment. Group 1 (N = 20) had general anesthesia and a towel head wrap. Group 2 (N = 18) had general anesthesia and wore no head cover. Group 3 (N = 6) had regional anesthesia and a towel head wrap. Group 4 (N = 2) had regional anesthesia and wore no head cover.

Postoperative recovery room treatment included the use of electronic warming blankets placed underneath and on top of the subjects with thermostats set at 38°C. Radiant heaters were also used (same intensity level for all patients).

Ventilated patients or those requiring supplemental oxygen received warmed, humidified oxygen at a consistent temperature level. Patients who required blood products or the administration of more than 500 cc. of intravenous fluid were excluded from the study.

Data were compared using a 2 X 2 factorial analysis of covariance to statistically control initial confounding group differences. It is clinically and statistically significant that the head-wrap group had higher temperatures 2 hours post-surgery than the no head-wrap group ($p = .0049$). Higher temperatures at time 1 were somewhat correlated with higher temperatures at time 9 ($r = .52$). Morgester claimed that smaller body mass ($p = .0006$) was correlated with higher temperature at time 9. However, the correlation ($r = -.04$) very weakly supports this conclusion. She also reported that

subjects with head insulation were significantly warmer 1 hour and 15 minutes postoperatively than the bare-headed subjects ($p = .01$). This result may have been associated with a phenomenon illustrated by Lunn (1969) following his observations of heat gain and loss during surgery and not associated with head insulation. He reported that patients increased heat production by 50 to 100 percent toward the end of the rewarming period and that such findings may be associated with increases in plasma catecholamine levels as the anesthetic wears off and the level of consciousness, muscular activity, and spontaneous respiratory rate increases. However, Morgester most likely prevented this from being a confounding variable by randomizing her subjects.

In a second postoperative study, Howell et al. (1992) examined the effects of two types of head coverings in the rewarming of patients after coronary artery bypass graft surgery during the initial 8-hour postoperative intensive care period. Eighty-one patients were randomly assigned to one of three treatment groups: towel head cover; towel and paper pad head cover; or no head cover. Rectal temperatures were recorded hourly for the first 8 hours. An analysis of variance revealed no significant differences ($p < .05$) between the three groups in the length of time required to reach normothermia or in the net temperature gain.

A major problem with this study design is that the

rewarming period actually begins in the operating room while the patient is still on cardiopulmonary bypass. By the time the postoperative cardiac surgery patient reaches the intensive care unit, there has already been opportunities for significant heat loss. In order to determine the effect of a head cover during the rewarming period, the experimental treatment must begin when rewarming begins.

Additionally, both Howell et al. (1992) & Morgester (1987) used rectal thermometry in their studies. In a non-research article, Phillips and Skov (1988) claimed that at temperatures less than 36.5°C, the rectal temperature reflects peripheral and not core temperature. Rectal temperature varies with blood flow to the rectum and the presence of fecal matter. Kruse (1983) also reported that rectal temperatures tend to measure surface rather than core temperatures. When Shvarts (1970) used rectal probes in his cooling hood study, he detailed precise placement of the probe at four inches into the rectum. Neither Howell et al. (1992) or Morgester (1987) accounted for these details in their reports which leads one to question the validity of the statistical findings.

Temperature Monitoring Site

The rewarming temperature trajectory of cardiac surgery patients may be influenced by the site of temperature monitoring and the reliability and validity of an instrument to monitor temperature. Consequently, this content must be

reviewed prior to conducting the proposed study to determine the most accurate method to monitor core temperature during rewarming.

During cardiac surgery, cooling and rewarming trends can influence the reliability of the site used for temperature measurement. A number of researchers have attempted to evaluate the accuracy of different temperature sites used to monitor core temperatures. Like many other researchers, Lilly, Boland, and Zekan (1980) suggested that there may be no "true core" temperature. They studied 31 adult patients (aged 24 to 71 years) who underwent a variety of major surgical procedures, including coronary bypass. They compared rectal, esophageal, and pulmonary artery temperature data with urinary bladder temperature (monitored via a Cath-Temp thermistor foley catheter with a LaBarge Mon-a-therm thermocouple) data collected at 15 minute intervals in the operating room, recovery room, and intensive care unit. Each of the units was calibrated against a mercury thermometer graduated in 2°C in a variable temperature water bath (Lilly, Boland, & Zekan, 1980, p. 742). The data from each probe were compared using least square linear regression analysis and revealed that temperatures at all sites during unassisted circulation were almost identical over a range of 28° to 38°C. It is statistically and clinically significant that during rapid rewarming on cardiopulmonary bypass (CPB), bladder temperature

increased at a rate very similar to that of the pulmonary artery ($R^2 = .914$). All the sampling sites had high correlation coefficients and statistically significant F values ($p < .0001$) over a broad temperature range (Lilly, 1987, p. 743).

Moorthy, Winn, Jallard, Edwards, and Smith (1985), also assessed urinary bladder temperature as an indicator of core temperature in patients rapid cooling and rewarming on cardiopulmonary bypass (CPB). Six men, average age 55 years old, and six women, average age 59.7 years were studied. Temperatures were monitored in the operating room in the nasopharynx (NPT), esophagus (ET), rectum (RT), bladder (UBT), and on the great toe. Pulmonary artery temperatures (PAT) were not monitored while the patient was on CPB because the researchers believed that possible errors could result from changes in pulmonary blood flow. After CPB, they monitored pulmonary artery, UBT, RT, and skin (ST) temperatures. They found that during rewarming on CPB, RT and UBT were significantly ($p < .05$) lower than NPT. It is clinically significant that in the intensive care unit PAT, UBT, and RT were similar. The statistical findings support UBT as a core temperature in the steady state.

Ramsay, Ralley, Whalley, DelliColli, and Wynands (1985) also observed that PAT, UBT, and RT lagged behind the NPT during rewarming. They defined the afterdrop concept as a

decrease in NPT after CPB and noted that the amount of afterdrop is inversely related to the adequacy of total body rewarming. To determine which commonly monitored "core" site accurately reflects total body rewarming, data were collected on 29 patients, 43 to 83 years old, who had uncomplicated valve or aortocoronary bypass surgery. Patients with peripheral vascular disease, insulin-dependent diabetes, or body weight 20 per cent above ideal were excluded from the study. The instruments used for temperature monitoring in the study were calibrated at 25°C and 40°C prior to data collection. Changes in RT, UBT, and PAT were correlated with NPT afterdrop ($p < .001$) by analyzing data collected at ten minute intervals from the start of rewarming to four hours post-bypass. It is clinically significant that after CPB was discontinued, the RT and UBT continued to increase while the PAT and NPT were decreasing. The UBT and RT were the only monitoring sites that showed a statistically significant correlation with afterdrop. The correlation was much more significant for the UBT ($p < .001$) than the RT ($.02 < p < .05$) (Ramsay et al., 1985, p. 610). The clinical significance of the data analysis is that 62 per cent of the variance in afterdrop can be predicted by the variance in the UBT at the termination of CPB. The authors noted that by 40 minutes after CPB and thereafter in the study, there was no statistically significant difference between the temperature

at any site and that there was a trend for the PAT to be the lowest temperature of all the sites 30 minutes after CPB. A clinically significant finding of this study is that the results support the UBT as the best monitor of total body rewarming during CPB and the early postbypass period.

Mravinac, Dracup, and Clochesy (1989) also proposed the use of UBT as a reliable indicator of core temperature during rewarming. They collected PAT, UBT, and RT data from 55 cardiac surgical patients during rewarming within one hour of admission to intensive care until their temperatures reached 37°C. Correlations for temperature sites varied during the course of rewarming: UBT and PAT had the best correlation ($r = .78$ to $.94$, $p < .01$) (Mravinac et al., 1989, p. 76). The strong correlation between UBT and PAT is different than the relationship described by Ramsay et al. (1985) who reported that the PAT tended to have the lowest temperatures 30 minutes post-bypass. The contrast in the findings may be related to the time interval over which monitoring took place. Recall that Ramsay et al. (1985) collected data from the start of rewarming to a four hour period post-bypass. Mravinac et al. (1989) collected hourly data on patients in the intensive care unit until their temperatures reached 37°C (approximately 7 hours). The results of this study also differ from the findings of Moorthy et al. (1985) who reported no significant differences in PAT, UBT, and RT measurements made in the

intensive care unit every hour for the first six hours and every two hours thereafter for ten hours. Mravinac et al. (1989) proposed possible explanations for the different results including: the depth of hypothermia (deep compared to moderate in the Moorthy et al. study); variations in rewarming methods that may have altered changes in heat transfer and heat loss in the body; and the level of temperature afterdrop may have contributed to differences in the patterns of temperature measurement. Mravinac et al. reported a UBT afterdrop from the operating room to the intensive care unit of 34.6°C to 33.5°C while Moorthy et al. reported no temperature drop. In fact, the mean temperatures at all sites on admission to the intensive care unit in the Moorthy et al. study were greater than 36.5°C and rose 1°C staying relatively constant over the ten hour study period. The similarity and high value of the temperatures between the three sites leads one to believe that total body rewarming may have already occurred in the Moorthy et al. study by the time the subjects were admitted to the intensive care unit.

The renal status was not mentioned in any of the research articles that were reviewed. The importance of evaluating this variable prior to UBT monitoring was raised by Earp (1989) in a review article. Urinary bladder temperature is an indirect index of blood flow, and may be subject to inaccuracies if the patient has preexisting renal disease or

is receiving diuretics (Earp, 1989, p. 271). Renal blood flow may be affected by changes in systolic blood pressure.

Hypotension is commonly associated with the rapid fluid shifts that occur during rewarming. In addition, mannitol is sometimes administered during cardiopulmonary bypass to ensure adequate renal perfusion. Consequently, simultaneous UBT and PAT monitoring may be indicated as the most reliable method to accurately evaluate the effect of head insulation on total body rewarming and the temperature trajectory in postoperative cardiac surgery patients.

Drugs That May Affect Thermoregulation

Anesthetic agents. Anesthesia promotes heat loss by depressing thermoregulatory function. Sufenta and fentanyl are both central nervous system depressants. Intraoperative doses of sufenta maintain cardiac output with slight reductions in the systemic vascular resistance postoperatively. Ethrane and forane are inhalation agents commonly used for general anesthesia during cardiac surgery. Shivering is cited as a potential adverse reactions of both of these drugs (Huff & Dowd, 1989). Propofol may decrease cerebral blood flow and increase cerebrovascular resistance (Olin, Hebel, Connell, Dombek, & Kastrup, 1991, p. 1303). Potential adverse reactions associated with ketamine (general anesthetic) include: elevated blood pressure and heart rate, hypotension, bradycardia, and enhanced skeletal muscle tone

(Olin et al., 1991, p. 1296).

Holtzclaw (1986) effectively summarized some of the effects of anesthetics on cardiac surgery patients. General anesthetics commonly promote vasodilation and suppress neuromuscular activity, thus antagonizing vasoconstriction and shivering - the body's two primary warming mechanisms. Neuromuscular blocking agents, including pavulon and norcuron, completely suppress shivering and may prolong rewarming. Holtzclaw also noted that anesthetized patients remain normothermic only in ambient room temperatures of 75°C and above (Holtzclaw, 1986, p. 293). Since most operating rooms are maintained at temperatures lower than 70°F, poikilothermic cardiac surgery patients are extremely vulnerable to heat loss.

Holdcroft and Hall (1978) considered similar heat loss mechanisms in their research on the effects of three anesthetic techniques on body temperature in 23 fit, fairly lean young women during microscopic fallopian tube surgery. The extraneous variables controlled in the design included: anesthetic techniques, operation length (3 hours), similarity of subjects, and ambient room temperature (75°F). The patients were randomly divided into three groups, receiving either halothane 0.5%, halothane 1%, or low-dose fentanyl as a supplement to nitrous oxide and myoneural block. No statistically significant difference was discovered between

the amount of heat loss in the three groups ($p > 0.1$). However, they remarked that heat loss was less with fentanyl than halothane (supporting data was not provided). There was also no statistical or clinical significance between temperature and the percentage of subcutaneous fat to body weight.

Morphine. Morphine is commonly used in postoperative cardiac surgery patients and can also potentially alter the rewarming rate. Rodriguez et al. (1983) reported a decrease in oxygen consumption, temperature, and urinary catecholamine excretion after morphine administration to hypermetabolic patients. They studied a group of 18 patients who underwent major intra-abdominal or intrathoracic surgery (not cardiac) after their admissions to intensive care (as long as their esophageal temperatures were less than 35.8°C). The control group ($N = 8$) was observed during routine medical management and received a mean morphine dose of $0.62 \text{ mg/kg} \pm 0.21 \text{ mg}$ postoperatively. The experimental group 2 ($N = 10$) received 1 or 4 mg/kg of morphine as an anesthetic in the operating room followed by a continuous infusion of 0.2 or 0.5 mg/kg/hr postoperatively. Group 2 patients were significantly ($p < .05$) older than control group patients. Nitroprusside was used during the postoperative period to control systolic blood pressure in at least 50 per cent of the patients in each group (which lessens the probability that this drug caused the

prolonged rewarming time in group 2). The most notable finding of this particular study was that there was an increased rewarming time when patients were on a morphine drip ($p < .025$). However, the significantly older age of the patients in group 2 could have extended rewarming times, making the validity of the results questionable. In addition, since cardiac surgery patients are rarely given morphine in this manner during rewarming due to the threat of fluid shifts, the findings would have been more clinically significant if the control group had not received any morphine. Nevertheless, morphine dosage should be monitored and considered as a clinically significant variable that could effect the rewarming trajectory because of its depressant effect on the central nervous system and as a vasodilator.

Nitroglycerine and nitroprusside. Nitroglycerine and nitroprusside may increase radiant and convective heat loss by increasing blood flow through capillary beds. Nobak and Tinker (1980) examined the incidence, time course, and magnitude of hypothermia following active rewarming on CPB to a NPT of 37°C in two groups of cardiac surgery patients. Group 1 (N = 20) was the control for group 2 (N = 8) who received nitroprusside during the rewarming period. CPB flows were increased during nipride infusion to maintain mean arterial pressures greater than or equal to 70 torr. Nipride did not alter the time required to reach a steady NPT post-bypass (45

minutes for both groups). It is clinically significant that warming blankets, type of cardiac surgery (valve repair versus coronary artery bypass), and anesthetic technique did not affect afterdrop in NPT. In addition, Nobak and Tinker (1980) reported that ambient temperatures between 64.4°F and 73.4°F did not affect afterdrop. An afterdrop in NPT of approximately 2.5°C occurred in all patients who did not receive nitroprusside during rewarming on CPB. The afterdrop in patients who received nitroprusside and increased pump flows was 42 per cent less than the control group ($\pm 1.5^{\circ}\text{C}$, $P < .01$). The clinical significance of the results is that nitroprusside may affect total body rewarming while the patient is on CPB. Patients who receive nitroprusside while on CPB could potentially have a faster rate of rewarming. Consequently, this extraneous variable must be considered when studying the effect of head insulation on the rate of rewarming.

Physiological Effects of Rewarming

Much has been written about the potential hazards of rewarming hypothermic patients. Chiara, Giomarelli, Bagioli, Rosi, and Gattinoni (1987) prospectively studied 16 patients undergoing hypothermic CPB for open heart surgery and reported that the first hours after open heart surgery represent a high-risk period for decompensation due to the discrepancy between increased metabolic needs and reduced cardiovascular

functioning. The goal of treatment is to ensure that oxygen supply to the tissues meets the demand. This can be affected by interventions to reduce heat loss.

Osguthorpe, Tidwell, Ryan, Paull, and Smith (1990) attempted to describe changes in temperature, arterial oxygen saturation (SaO_2), cardiac index (CI), oxygen consumption (VO_2), and mixed venous oxygen saturation (SVO_2) over the initial four hour rewarming period in thirty-six patients having coronary artery surgery. The most statistically significant finding was a negative relationship between mean PAT and SVO_2 data (Pearson's correlation, $r = -.88$). It is clinically significant that as the temperature increased postoperatively, the SVO_2 decreased. Peripheral dilatation that occurs during rewarming allows more oxygen to be delivered and consequently, consumed by the tissues during cellular metabolism. In addition, metabolism increases as temperature increases. These physiological changes may account for a lower SVO_2 .

Shivering. Thermoregulatory function returns during rewarming as neuromuscular blockade and anesthesia wears off. Theorists believe that shivering occurs as a result of hypothalamic integration of messages from cold thermoreceptors in the skin, brain, and spinal cord and that an increase in thermal gradients between skin and core temperatures may trigger the shivering response (Earp, 1989). Shivering may

cause increased metabolic and circulatory demands in patients who already have compromised cardiac function. In two non-research articles, Earp (1989) and Holtzclaw (1986) reviewed the effects of shivering. Earp (1989) claimed that shivering lacks heat generating efficiency while it dramatically increases the myocardial workload and consequently, the myocardial oxygen consumption. Holtzclaw (1986) explained that shivering muscles produce lactic acids which are unable to undergo hepatic degradation due the decreased enzymatic efficiency associated with hypothermia. The accumulation of by-products of anaerobic metabolism with carbon dioxide and fixed acids entering the circulation from previously unperfused capillary beds can cause serious metabolic acidosis for postoperative patients. The costs to the shivering patient in terms of metabolic demands and oxygen consumption are extremely high in comparison to its relatively low heat generating efficiency.

Age and Rewarming

Vaughan, Vaughan, and Cork (1981) wanted to determine if there was a relationship between age, anesthesia, and shivering to rewarming. They conducted a prospective, descriptive study of 198 postsurgical patients (85 men and 113 women) greater than or equal to 17 years old (mean age of 50.0 ± 1.3 years). Patients were excluded if they had: craniotomies, cardiac surgery, coagulation defects,

preoperative hyperthermia, or previous tympanoplasty. Core body temperatures were measured with a tympanic membrane thermometer (Mon-a-Therm, accuracy $\pm 0.27^{\circ}\text{C}$) every 15 minutes from admission to recovery room discharge (Vaughan et al., 1981). Elderly patients (greater than 60 years old, $N = 62$) had statistically significant lower admission and discharge temperatures ($p < .05$). The clinical significance is that the duration of hypothermia was longer for elderly patients. However, neither the rate of increase in temperature nor length of recovery room stay were statistically different ($p < .05$) between the two age cohort groups (Vaughan et al., 1981, p. 748). There were no statistically significant differences between the cohort groups in regard to sex, height, body surface area, anesthesia, or surgical time. There were statistically significant differences ($p < .05$) in weight, body mass index, and operative procedures (the younger cohort group included 30 obese patients undergoing gastric stapling surgery). The most clinically significant conclusion reached was that elderly patients demonstrate a decreased ability to quickly regain thermoregulatory function.

Rewarming Methods

Vaughan, Vaughan, and Cork (1980) also evaluated three external rewarming methods for their effectiveness in raising body temperature by secondary data analysis of the sample population cited in the Vaughan et al. (1981) study. The

sample was divided into four rewarming groups: group 1, radiant heat lamps; group 2, warmed blankets, without change; group 3, warmed blankets, changed every 30 minutes; group 4, blanket applied at room temperature and humidity. The results showed that the rewarming method did not statistically affect ($p > 0.1$) length of stay in recovery room, rate of temperature rise in the first postoperative hour, duration of hypothermia, or discharge temperature.

In a more recent article, Sessler and Moayeri (1990) tried to determine the efficiency of four postoperative warming devices using five healthy, unanesthetized volunteers. The mean age of the three female and two male non-obese subjects was 30 ± 4 yr. Heat flux transducers were placed on ten skin-surface sites to measure heat loss or gain via radiation, convection, and conduction.

Thermal steady state occurs when metabolic heat production equals heat loss to the environment (Sessler & Moayeri, 1990). The basal metabolic rate of humans produces a total heat flux (W) of approximately 100 ($1 \text{ W} = 0.86 \text{ kcal/hr}$ (Sessler & Moayeri, 1990)). In patients with normal metabolic heat production mean body temperature will remain normal when 90 W is lost to the environment. Increasing mean body temperature 1°C per hr (in individuals with normal metabolic function) only requires preventing the environmental heat loss. These investigators claim that in the absence of

thermoregulatory responses (in anesthetized patients), the mean body temperature would be expected to decrease by 0.25°C per hour. Consequently, all potential sources of heat loss should be minimized or prevented.

The warming devices included: a pair of 250 watt infrared heating lamps mounted 71 cm above the abdomen; a 500 watt "Thermal Ceiling" set on high, mounted 56 cm above the subjects; a water blanket, set to 40°C; and the Bair Hugger warmer set on 33°C, 38°C, and 43°C. It is clinically significant that the Bair warmer (set on low or medium) and the water blanket each decreased cutaneous heat loss to nearly zero. In addition, the Bair warmer (all settings) and the water blanket raised skin temperature more than the radiant heaters ($p < .05$). Sessler and Moayeri (1990) claimed that Bair Hugger set on medium was more effective than each radiant warming device and as effective as the circulating water blanket in regard to heat transfer across entire skin surface. Set on high, the Bair Hugger transferred the most heat of all the methods studied (mean body temperature increase: 1.5°C per hour).

Imrie, Ward, and Hall (1991) randomly assigned 30 patients after coronary artery bypass to one of three groups: a control group that received no active rewarming; an esophageal group, rewarmed with the Exacon TT8200 thermal therapy system; a radiant group, rewarmed with the Aragona

mobile thermal ceiling (heating surface mounted approximately 1 m above the patients). Postoperatively, all patients were covered to the waist with aluminized reflecting blankets. Ambient, tympanic membrane, and skin temperatures were measured every 15 minutes until the patients temperature reached 37°C and continued for two hours after rewarming was stopped.

The mean skin temperature in the radiant group was significantly higher than those in the other two groups during the rewarming period ($p < .05$) and the postrewarming period ($p < .01$). The authors note that they observed less shivering in the radiant group than the other two groups despite the fact that the total shivering scores for all three groups during the whole study period were not significantly different. Imrie et al. (1991) suggest that radiant overhead heaters will suppress thermoregulatory shivering by stimulation of cutaneous thermoreceptors. They propose that this rewarming method reduces the need for intrinsic heat production by the patient and increase heat gain from the environment.

A rewarming strategy. To reestablish heat balance during rewarming, heat gained must equal the heat lost during surgery and bypass. Shivering generates heat that the patient cannot retain. Vigorous skeletal muscle activity increases circulation through cold vascular beds, and heat loss is

facilitated by convection created by body movement (Holtzclaw, 1986, p. 295). Drugs given to prevent vasoconstriction and shivering during rewarming result in general vasodilation and a tendency toward tachycardia and hypotension. These effects decrease insulation in the periphery and shunting so that heat is lost more quickly, contributing to core temperature drift and afterfall (Abbey et al., 1973).

Despite differences between core and surface cooling, Abbey's plan for decreasing shivering in surface cooled patients seemed relevant to Holtzclaw (1986). Holtzclaw used it to design a plan of care for shivering (core cooled) hypothermic cardiac surgery patients. Abbey suggested goals for nursing intervention based on physiological principles of heat loss and the shivering stimulus. Three of these goals have implications for the proposed study on head insulation: restoring lost heat, modifying the rate of heat loss, and drug suppression of shivering.

Holtzclaw (1987) explained that the large heat deficit that occurs during cardiac surgery must be restored or shivering will be stimulated during rewarming at great cost to the patient. Rewarming on CPB results in a transient increase in core temperatures. Peripheral vasculature may remain constricted for 30 to 40 minutes postbypass and does not receive warmed blood (Holtzclaw, 1986). Core temperature afterdrop occurs when heat transfer begins to take place

between the core and the periphery. Slow uniform rewarming is recommended to prevent rapid increases in metabolic demands, oxygen consumption, and acidosis. The internal and external transfer of heat using warmed humidified gases, heated blankets, warmed intravenous fluids, and radiant lamps has not been particularly successful in restoring heat to centrally cooled patients (Ralley et al., 1984). To increase the efficiency of these rewarming methods, drugs are frequently added to suppress shivering and promote vasodilation. Abbey and Holtzclaw agree that using dry protective covering and shivering suppressants may reduce the rate of heat loss during rewarming. To summarize, the restoration of and protection from heat loss become clinically significant during drug-induced hypothermia.

Summary

This literature review was an attempt to clarify the problem of heat loss in postoperative cardiac surgery patients. Physiological research revealed the absence of vasoconstrictor reflexes in the head and demonstrated significant heat loss from this area of the body (Froese & Burton, 1957; Hertzman & Roth, 1942; Shvartz, 1970). Three studies investigated the usefulness of head insulation for general surgery patients during the intraoperative, perioperative, and postoperative periods (Biddle & Biddle, 1985; Erickson & Yount, 1991; Morgester, 1987). Only one

study examined the effect of head insulation (postoperatively) for cardiac surgery patients (Howell et al., 1992).

Two of the studies found head insulation clinically useful. Overall, the results suggest that head insulation may significantly decrease heat loss, particularly in the elderly, and that it warrants further investigation. Cardiac surgery patients are often more vulnerable to the potential hazards that exist during the perioperative rewarming period. Consequently, head insulation should be pursued further as an adjunct to conventional rewarming methods in this patient population.

There is controversy in the literature over which temperature monitoring site accurately reflects core body temperature. Some authors suggest that UBT monitoring is the most accurate reflection of total body rewarming and that this should be considered instead of monitoring core temperature alone. To ensure accuracy of the rewarming temperature trajectory and add validity to any findings, a synopsis some of the available research on this subject was included in this literature review.

In addition, the review included an exploration of the extraneous variables that could potentially prolong the rewarming time of cardiac surgery patients. The relationship between anesthetic agents, morphine, intravenous nitrates and thermoregulation was examined. An analysis of the detrimental

effects of shivering in postoperative cardiac surgery patients was included to emphasize the importance of efficient rewarming. Research studies on forced air, warming blankets, and radiant lights addressed the efficiency of external mechanisms to restore heat lost during induced hypothermia.

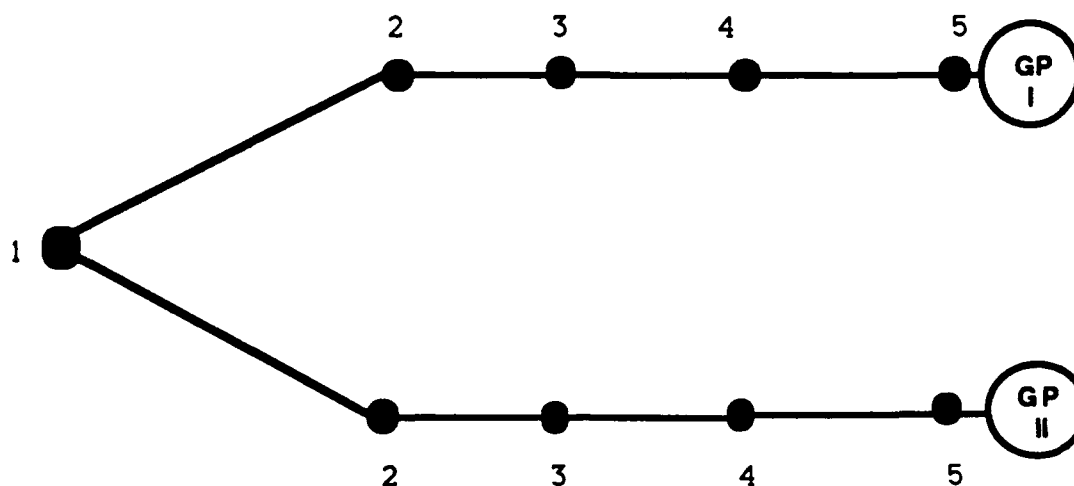
CHAPTER III

Methods

Design

A quasi-experimental pre-test, post-test design was used for this study. One independent variable, head insulation, was manipulated by the researcher. The dependent variable was total rewarming time. The subjects were randomly divided into a control group and an experimental group. Baseline urinary bladder temperature data was recorded on all patients in the operating room just prior to the start of the rewarming period. Head insulation was placed on patients in the experimental group at this time and data was collected at designated time intervals throughout the rewarming period in the operating room and during the postoperative period in the intensive care unit until subjects' UBT reached 36.5°C. If the subjects' UBT was greater than 36.5°C on admission to intensive care, that temperature was recorded as the final temperature. Head insulation was removed from the experimental group subjects when their temperatures reached 36.5°C. The total rewarming time was defined as the difference between the time when the patient started rewarming on cardiopulmonary bypass in the operating room (OR) until the UBT reached 36.5°C (97.7°F) in the Cardio-thoracic Surgical Intensive Care Unit (CTSICU). The study design is depicted in the figure on the next page.

Figure. Pretest-posttest design used for study.



GP I = experimental group, wore head insulation

GP II = control group, did not wear head insulation

- Time: 1 = Initial UBT at start of rewarming
subject was still on cardiopulmonary
bypass; random assignment to groups and
experimental treatment.
- 2 = UBT at cardiopulmonary bypass termination.
- 3 = UBT when operative procedure and surgical
sternal closure was complete.
- 4 = Initial UBT (within 5 minutes of arrival)
in CTSICU.
- 5 = UBT at 36.5°C, discontinued active external
rewarming measures and head insulation.

Control of Extraneous Variables

To control for environmental factors and anesthetic and operative techniques, data collection was restricted to one medical facility. The investigator monitored environmental factors that could potentially contribute to radiant and convective heat loss and attempted to control this for all subjects. It was recognized that evaporative heat loss occurs while the chest cavity is open. The time interval during which the chest remained open post-bypass was monitored, compared, and considered in the analysis of the results for all subjects.

Standard treatment for all study subjects included the following: (a) paper surgical caps (infection control policy) until rewarming was started when subjects were divided into experimental and control groups (the paper surgical cap was removed from the control group as soon as the subject left the operating room); (b) posterior upper torso warmed during the perioperative rewarming period with a warming blanket set on 38°C; (c) after chest closed in the operating, covered with one warmed blanket and a Thermadrape (aluminized polyethylene) sheet until arrived in CTSICU; (d) covered from the toes to just above the pubic area with a blanket and the Thermadrape sheet during the rewarming period in the CTSICU; (e) warmed with an Ohio overhead radiant warming unit (high intensity) in the CTSICU postoperatively; and (f) the ventilator cascade

heat setting monitored in the CTSICU. Addition of the Thermadrape sheet during the rewarming period is the only treatment that was added to the standard rewarming protocol currently used in the CTSICU at the study site.

Population and Sample

The population for the study was all patients undergoing coronary artery bypass surgery requiring induced hypothermia in a large military hospital in South Central Texas. A convenience sample of 38 subjects was selected from the study population over a seven month period. Group I (N = 19) wore a Thermadrape cap from the start of rewarming in the OR; group II (N = 19) wore a paper surgical cap (infection control standard, minimal insulative efficiency (Biddle & Biddle, 1985)) in the OR and no head covering in CTSICU during the rewarming period. Candidates were selected on the day preceding their scheduled surgeries. The following criteria was used to select the sample:

1. Male or female age 21 to 75 years.
2. No known history of peripheral vascular disease (as documented in the medical record).
3. No known history of kidney disease, preoperative serum creatinine ≤ 1.5 mg/dl (as documented in the subject's medical record).
4. Preoperative oral temperature (36.0°C to 37.9°C) the day before surgery.

5. Urinary bladder catheters with thermistors in place prior to hypothermia induction in the OR.
6. Presence of a radial or ulnar arterial line capable of measuring continuous arterial pressure.
7. Permission of cardiothoracic surgeon.
8. Subject could read and understand English.
9. Subject voluntarily agreed to participate in study.

Procedures

Setting

The study was conducted in the OR and in the CTSICU at a large military hospital in South Central Texas. All subjects were studied in individual rooms in the CTSICU.

Randomization of Sample

Subjects were randomly assigned to either the control or experimental group. Because the original intent was to study forty subjects, volunteers were randomized to groups in four blocks of ten. For each block of ten subjects five pieces of paper indicating control group and five pieces of paper indicating experimental group were placed in blank envelopes and sealed. The envelopes were shuffled and the numbers one through ten placed on the envelopes indicating group assignment. As patients were entered into the study,

envelopes were assigned to patients in ascending numerical order. The envelopes were prepared and identified by block letter A, B, C, or D and ascending numerical order prior to initiation of data collection. Each envelope was opened by this investigator prior to entering the OR to collect data in ascending alphabetical and numerical order.

Data Collection Procedure

The following procedure was used for data collection:

1. On the day prior to surgery the investigator:
 - a. Obtained consent from each patient to enroll him or her in the study (Appendix B).
 - b. Recorded subject's oral temperature with a Diatek thermometer.
 - c. Collected demographic data, and preoperative creatinine.
2. On the day of surgery:
 - a. Opened envelope to assign patient to experimental or control group.
 - b. Calibrated urinary bladder temperature monitor to the manufacturer's specifications and connected to urinary bladder catheter thermistor.
 - c. Recorded data as specified on data collection sheet (Appendix C) at the start of rewarming while patient was still on cardiopulmonary bypass (CPB).

- d. Placed Thermadrape cap on experimental group patients when the perfusionist indicated that rewarming had started.
- e. Recorded data as specified on data collection sheet (Appendix C) when CPB was discontinued.
- f. Recorded data as specified on data collection sheet when chest was surgically closed.
- g. Placed one warmed cotton blanket followed by a Thermadrape sheet over patient from neck to toe.
- h. Moved patient to CTSICU bed from OR table.
- i. Removed paper surgical cap from control group.
- j. Transported patient to CTSICU.
- k. Recorded initial data as specified on data collection sheet (Appendix C) on arrival to CTSICU.
- l. Checked level of arterial line transducer and calibrated equipment.
- m. Within 15 minutes of arrival to CTSICU placed radiant warmer (left wheels on unit placed on right side of front wheel at head of bed - patient's left side) 30 inches above subject's skin surface. Set device on "non-servo," high-intensity.
- n. After allowing the radiant warmer to warm for five minutes, removed cotton blanket and

Thermadrape sheet. Replaced one cotton blanket (folded in half) followed by the Thermadrape sheet over the subject's lower body (from toes to just above the pubic area).

- o. Recorded remaining data on the Data Collection Worksheet (Appendix C).
- p. When subject's UBT reached 36.5°C, recorded time, collected any final data, removed cap and covering over lower half of body, covered the patient from neck to toe with one cotton sheet and a room temperature cotton blanket, and discontinued radiant warming treatment.

Criteria for discontinuing study. During the study, the following criteria served as a guide for the researcher to terminate data collection and remove the reflective cap:

1. Request from subject to be withdrawn from the study.
2. Patient re-cooled and heart re-arrested for a second time intraoperatively.
3. Postoperative mediastinal/chest tube drainage > 100 ml/hour for four hours.
4. Postoperative cardiac arrest during data collection period.
5. Patient returned to OR for any reason.

Instrumentation

Preoperatively, all subject's oral temperatures were measured with a Diatek electronic thermometer. The manufacturer specified accuracy of this device is ± 0.1 to $\pm 0.2^{\circ}\text{C}$ within a temperature range of 28.9 to 42.2°C . Ambient room temperatures in the OR and individual patient rooms in the CTSICU were measured with a room temperature thermometer traceable to the National Bureau of Standards. The urinary bladder temperature was monitored as an indicator of core and total body rewarming after induced hypothermia. Mon-a-therm urinary bladder thermistor catheters were thermocoupled to a Mon-a-therm UBT monitor during the study (Mallinckrodt, Inc., St. Louis, Missouri). The manufacturer specified accuracy for this instrument is $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$).

Pulmonary artery temperatures (PAT) were monitored in the OR and CTSICU with either the Spectramed Pentacath pulmonary artery catheter (Model SP5507) (manufacturer specified thermistor accuracy $\pm 0.1^{\circ}\text{C}$) or the Oximetrix Opticath fiberoptic pulmonary artery catheter (manufacturer specified thermistor accuracy $\pm 0.3^{\circ}\text{C}$ within a range of 25 to 40°C). These catheters were thermocoupled to a Marquette monitor series 7010 cardiac output module. Marquette Electronics reported blood temperature accuracy of this equipment at $\pm 0.2^{\circ}\text{C}$.

Thermadrape caps and sheets (OR Concepts, Inc., Roanoke,

Texas) were used during the rewarming period to minimize potential sources of heat loss. These products are made of an aluminum-coated polyethylene material that is lightweight, flexible, not subject to tearing, and is electrically nonconductive (Erickson & Yount, 1991).

An Ohio Radiant Warmer (Ohio Medical Products, Madison, Wisconsin) was used to warm subjects in the CTSICU. Use of this device is part of the standard CTSICU rewarming protocol at WHMC. The warmer consists of two banks of infrared heating elements spaced approximately 15 inches apart. These were positioned directly above and parallel to the subject's skin surface.

Data Analysis

The independent variable in this study, head insulation is a nominal measure. Total rewarming time, the dependent variable, is a ratio-level measurement. Based on a retrospective analysis of total rewarming times of 21 patients who underwent coronary artery bypass surgery at the data collection site one year prior to data collection, a preliminary statistical power analysis was performed. Based on a 0.05 level of significance for a one-tailed t-test, it was determined that a sample size of 17 subjects per group would yield a statistical power of 0.69. To increase the chance of detecting group differences, a sample size of twenty subjects was proposed for each of the two groups.

Demographics of the sample were described using descriptive statistics. Considering the possibility that head insulation could lengthen or shorten total rewarming time, a two-tailed t-test ($p < .05$) was used to compare experimental and control group differences.

Limitations

The limitations of a study of this nature have to do with the complexity of the coronary artery bypass procedure and perioperative circumstances. The individual nature of the multi-system response to general anesthesia and heart-lung bypass may be influenced by a variety of factors including: age, sex, prior medical and surgical (including prior cardiac surgery) history, or operative and perfusion techniques. The role that these variables play is difficult to anticipate or control. The physiological responses to the drugs used during the perioperative and postoperative period may vary greatly between patients. Based on the review of the literature, some of these drugs (morphine, nitroglycerine, and nitroprusside) may influence the postoperative temperature trajectory. In addition, volume replacement with room temperature fluids may affect the rate of rewarming. This practice is almost always required for this patient population, because of frequent rewarming intravascular fluid shifts. It is difficult to set limits on room temperature volume replacement because it is so individual.

Since the factors mentioned are so prevalent in this patient population, it was feared that the exclusion of patients for any of these would severely limit the sample size. Consequently, this data was collected (Appendix C) and considered in the analysis of the results.

Threats to Internal and External Validity

In this study a possible threat to internal validity was primarily due to sample selection. A convenience sample was selected to expedite the data collection. To minimize this threat, patients were randomized into a control and experimental group and a pretest-posttest design was used.

This same selection process was most likely the primary threat to external validity. This may jeopardize the generalizability of the findings to other settings. The randomization of the study subjects into the two groups was an attempt to diminish this threat to external validity.

Ethical Considerations and Protection of Subjects

This investigator met with potential subjects (and their family members, when possible) the day prior to their scheduled coronary artery bypass surgery and verbally explained the nature of the study to the subjects. Time was allowed to answer any questions that they, their family members, or significant others may have. Written informed consent was obtained from the subject. The first copy of the original consent form (Appendix B) was sent to Wilford Hall

USAF Medical Center's (WHMC's) Clinical Investigation Directorate for maintenance with the protocol file, the second was given to the subject, the third copy was placed in the subject's chart, and the fourth copy was maintained by the investigator. Subjects were identified by numbers on the data collection sheets. This information will remain confidential and will only be released to subjects' cardio-thoracic surgeon when necessary and requested by the same. Otherwise, patient privacy will be protected according to the Federal Privacy Act statement for the records (Department of Defense Form 2005).

Permission to conduct the study was obtained prior to data collection from The University of Texas Health Science Center at San Antonio Institutional Review Board (Appendix A), the Chairperson of WHMC's Department of Operating Room Services, the Chairperson of WHMC's Department of Surgical Nursing, the Chairperson of WHMC's Nursing Clinical Investigations Council, the Chief, Division of Nursing at WHMC, the Clinical Investigation Directorate at WHMC (Appendix A), and the Office of the Surgeon General of the United States. The research protocol was reviewed with the Chief of WHMC Cardiothoracic Surgery and the CTSICU charge nurse. In addition, an inservice was provided for staff nurses and medical technicians to secure their cooperation and support with the study. A pilot test of the research design was conducted on the first two subjects. This served to determine

whether or not revisions were necessary in any aspect of the proposed project.

In summary, this chapter has detailed the methodology for the proposed study. The proposed design was based on the investigator's clinical expertise with this patient population as well as information obtained from the review of the literature. Retrospective data was collected on coronary artery bypass surgery patients, enabling the consulting statistician to perform a power analysis and arrive at the proposed sample size. The setting, data collection procedure, and instrumentation was detailed to allow for future replication of the study design. An attempt was made to identify limitations of the study including potential threats to validity. Finally, ethical considerations were addressed, including the manner in which the investigator attempted to protect participants in the study.

CHAPTER IV

Results

Overview

This chapter will report the results of a quasi-experimental study in which coronary artery bypass surgery patients were monitored to determine the effect of head insulation on total rewarming time. The investigator originally enrolled 35 male and 3 female adult patients from a large military hospital in South Central Texas in the study. A number of potential subjects were ineligible to participate in the study: one individual who had just received a narcotic analgesic could not sign the consent form; seven individuals had peripheral vascular disease; five had a history of renal disease or a creatinine > 1.5 mg/dl; and three individuals were greater than 75 years old. There was also attrition of several subjects after they had been enrolled in the study: 2 were withdrawn due to excessive bleeding; 2 subjects were withdrawn due to hemodynamic decompensation; 1 subject was discontinued due to recooling on cardiopulmonary bypass; 1 subject was withdrawn when the foley catheter was misplaced; and 1 subject was withdrawn when the temperature thermistor on the foley catheter was inadvertently cut off by an operating room nurse.

Patients undergoing coronary artery bypass surgery for a second time ("redo") were not originally excluded as

potential candidates for the study because of the concern that the patient population would be limited. However, this subpopulation was not as large as anticipated. Analysis revealed that only two such patients were selected for the study and both were randomized to the control group. It was discovered that the surgical procedure was much more complex for both of these patients. They had more surgical and nonsurgical blood loss and required longer cardiopulmonary bypass runs than first-time cardiac surgery patients. Consequently, it was decided to exclude these patients from the final data analysis.

In the final analysis Group I, the experimental group, (17 males and 2 females) wore aluminized polyethylene caps during the rewarming period in the operating room and CTSICU. Group II, the control group, (16 males and 1 female) wore paper caps in the operating room and no head cover in the CTSICU. Four Group I subjects and two Group II subjects were $\geq 50\%$ bald; two Group I and three Group II subjects had $< 50\%$ baldness; twelve subjects in Group I and twelve in Group II had short hair; and one Group I subject had medium length hair. The remaining preoperative demographic and other data are summarized in Tables 1 and 2.

Demographic and other data collected during the rewarming period in the OR and the CTSICU are summarized in tables 3 and 4. The mean time interval between termination of

cardiopulmonary bypass and patient arrival in the CTSICU was calculated for each group: Group I - 82.84 ± 17.82 minutes and Group II - 73.35 ± 12.48 minutes. Various pharmacologic agents were used on study subjects during the rewarming period. A drug use summary for the sample population may be found in Table 5.

Table 1

Preoperative Data (demographic and other) on Subjects in
Groups I and II

<u>Variables</u>	<u>M</u>	<u>SD</u>	<u>Range</u>
<u>Group I - Experimental</u>			
Age	62.58	7.28	42 - 75
Height (cm)	175.79	10.88	150 - 200
Weight (kg)	87.4	13.46	59 - 116
BSA	2.04	0.19	1.6 - 2.38
BUN	18.50	5.28	8 - 30
Creatinine	1.27	0.14	1 - 1.5
Ejection Fraction	58.13	17.57	22 - 78
Temperature (°C)	36.29	0.20	36 - 36.7
<u>Group II - Control</u>			
Age	62.12	8.92	43 - 73
Height (cm)	175.29	8.20	157 - 188
Weight (kg)	84.36	10.26	67 - 98
BSA	2.01	0.13	1.8 - 2.23
BUN	17.94	5.03	11 - 27
Creatinine	1.19	0.21	0.8 - 1.5
Ejection Fraction	59.73	10.43	45 - 75
Temperature (°C)	36.51	0.32	36.1 - 37.2

Table 2

Preoperative Medical/Surgical History of Subjects

<u>Medical/Surgical Diagnoses</u>	<u>Group I</u>	<u>Group II</u>
	<u>Experimental</u>	<u>Control</u>
<u>Past Medical History</u>		
Congestive Heart Failure	1	0
COPD	4	0
CVA	0	2
Diabetes Mellitus	6	4
Gout	2	1
Hypercholesterolemia	11	8
Hypertension	8	11
Myocardial Infarction	3	4
Rheumatoid arthritis	0	1
Osteoarthritis	0	1
Thrombocytopenia	1	0
<u>Past Surgical History</u>		
Partial Thyroidectomy	1	0
Prostatectomy	0	1
Cholecystectomy	1	2
AAA Repair	0	1
Nephrectomy	1	0

Table 3

Perioperative Rewarming Data on Group I (Experimental)

<u>Variables</u>	<u>Mean</u>	<u>SD</u>	<u>Range</u>
Crystals (cc)	3360.31	1233.61	1925 - 6032
Colloids (cc)	1940.0	736.72	1000 - 3815
Warmed Fluids (cc)	1473.68	1145.08	0 - 4000
Grafts	3.74	1.33	1 - 7
Cross Clamp (min)	69.16	23.45	23 - 122
Bypass (min)	119.11	36.95	43 - 190
Postop PCO ₂	38.21	5.12	30 - 54
Postop BUN	14.95	4.21	10 - 25
Postop Creatinine	1.06	0.15	0.8 - 1.5
CTSICU Vent Temp (C)	31.79	1.81	28 - 36
Chest tube output	300.53	193.58	0 - 800
OR Temp (F)	71.2	2.1	68 - 75
CTSICU Temp (F)	75.2	1.67	73 - 77

Table 4

Perioperative Rewarming Data on Group II (Control)

<u>Variables</u>	<u>Mean</u>	<u>SD</u>	<u>Range</u>
Crystals (cc)	2969.40	745.53	1970 - 4130
Colloids (cc)	1803.03	473.75	750 - 2530
Warmed fluid (cc)	1529.41	1377.39	0 - 4400
Grafts	3.71	1.16	1 - 6
Cross clamp (min)	64.82	19.09	29 - 94
Bypass (min)	112.06	29.49	48 - 155
Postop PCO ₂	36.94	5.19	29 - 47
Postop BUN	13.35	3.74	8 - 20
Postop creatinine	1.0	0.18	0.7 - 1.4
CTSICU vent temp(C)	31.94	1.29	30 - 35
Chest tube output	297.0	173.79	25 - 600
OR Temp (F)	71.5	1.95	69 - 75
CTSICU Temp (F)	75.25	1.25	73 - 77

Table 5

Percentage of Subjects in Each Group that Received Specific
Drugs During the Perioperative Period

<u>Drug</u>	<u>Group I</u> <u>Experimental</u> <u>(n = 19)</u> %	<u>Group II</u> <u>Control</u> <u>(n = 17)</u> %
<hr/> <u>Anesthetic Agents</u>		
Fentanyl	26.3	29.4
Sufenta	68.4	64.7
Forane	78.9	64.7
Ethrane	52.6	47.0
Ketamine	57.8	29.4
Propofol	10.5	0.0
<u>Analgesics and Stat Meds</u>		
Morphine	78.9	82.4
Valium	5.3	11.8
Versed	36.8	35.3
<u>Paralytics</u>		
Norcuron	36.8	35.3
Pavulon	95.0	76.5
<u>Diuretics</u>		
Lasix	0.0	11.8
Mannitol	10.5	23.5

Table 5 (continued)

<u>Drug</u>	<u>Group I</u> <u>Experimental</u> <u>(n = 19)</u> %	<u>Group II</u> <u>Control</u> <u>(n = 17)</u> %
<hr/> <u>Intravenous Vasopressors</u>		
Dopamine	42.1	23.5
Dobutamine	5.3	0.0
Nipride	84.2	82.4
Nitroglycerine	100.0	100.0
Arfonad	5.3	5.9
Neosynephrine	84.2	88.2
Epinephrine	5.3	0.0
Esmolol	31.6	29.4
Lidocaine	10.5	11.8

Hypothesis Testing

Hypothesis. Hypothermic postoperative cardiac surgery patients wearing head covers will require less total rewarming time to reach a urinary bladder temperature of 36.5°C (97.7°F) than hypothermic postoperative cardiac surgery patients not wearing head insulation.

Urinary bladder temperatures and times were recorded from each subject at six different intervals: at the start of rewarming in the OR (time 1); discontinuation of bypass; when the chest was surgically closed; on arrival to CTSICU; and when the patient reached at least 36.5°C in CTSICU (time 5). The statistics on total temperature change, total rewarming time, and rate of change in temperature are found in Table 6.

A two-tailed t-test of mean total rewarming times ($T = T_5 - T_1$) revealed no significant difference in the variance between the experimental and control groups (Table 7). Therefore, the experimental hypothesis was rejected in favor of the null hypothesis. Analysis of the data revealed that T_1 was quite different for many of the subjects in the study. Since each patient had a different distance to rewarm, further analysis of mean rate of temperature change by group was performed. A two-tailed t-test revealed no statistically significant differences between the experimental group and the control group for mean rate of change in urinary bladder temperatures (Table 7).

Table 6

Means, Medians, Standard Deviations, and Ranges for Groups I and II on Rewarming Measurements

<u>Variable</u>	<u>Mean</u>	<u>SD</u>	<u>Median</u>	<u>Range</u>
<u>Experimental Group I</u>				
Rewarm Time (min)	209.63	39.21	212.0	126 - 285
Total Temp Change (C)	6.89	1.82	6.9	4.1 - 11.2
Rewarming Rate °C/min	.0338	.0109	.0310	.0206 - .0611
<u>Control Group</u>				
Rewarm Time (min)	216.94	54.18	219.0	99 - 316
Total Temp Change (C)	6.91	2.21	7.8	0.5 - 9.0
Rewarming Rate °C/min	.0313	.0086	.0333	.0051 - .0424

Table 7

Group Differences in Rewarming Variables with T-tests

<u>Variable</u>	<u>Mean</u>	<u>t</u>	<u>DF</u>	<u>2-Tail</u>
	<u>Difference</u>	<u>Value</u>		<u>Prob.</u>
<hr/>				
Temp				
Change °C	.0223	-.03	34	.974
<hr/>				
Rewarm				
Time (min)	7.31	-.47	34	.643
<hr/>				
Rewarming				
Rate °C/min	.0025	.77	34	.447
<hr/>				

CHAPTER V

Discussion of Results

Discussion

Based on an extensive review of the literature which supported the use of head insulation to decrease perioperative heat loss, a quasi-experimental study was conducted to determine whether this intervention would enhance the efficiency of the methods currently used to rewarm postoperative coronary artery bypass graft surgery patients at a large military medical center in South Central Texas.

The sample consisted of 35 male and 3 female patients between the ages of 42 and 75 years. Two control group subjects, who underwent coronary artery bypass surgery for a second time were excluded from the data analysis because of noted increased complexity of the surgical procedure and recovery period.

After random assignment to experimental and control groups, exact times and urinary bladder temperatures were recorded by the investigator at five specific times during rewarming: (1) at the start of rewarming on CPB; (2) when CPB was discontinued; (3) when the subjects' chest cavities were surgically closed; (4) on arrival to CTSICU; and (5) when the subjects' UBT reached 36.5°C to determine whether or not subjects wearing head insulation would require less total rewarming time. If subjects' UBT was > 36.5°C on arrival to

CTSICU, this time and temperature were recorded as final data measurements.

The descriptive statistics demonstrated that the experimental and control group were very similar with regard to age, height, weight, BSA, preoperative BUN and creatinine, ejection fraction, and preoperative oral temperature. In regard to past medical and surgical histories, the two groups were also very similar. During the rewarming period, the mean use of crystalloids, colloids, and warmed intravenous fluids by the two groups was almost the same. Both groups had similar mean cross clamp and cardiopulmonary bypass times. All postoperative patients had adequate renal perfusion, as indicated by normal postoperative BUN and creatinine levels. The groups had similar mean amounts of blood loss from the mediastinal and chest tubes. Finally, the mean room temperatures in the operating room and the CTSICU were very similar for each group.

Overall, there were no major differences between the groups in the types of drugs or in the percentages of patients that received various drugs (see Chapter IV, Table 5). It is remarkable that the most notorious vasodilating agents (morphine, nitroglycerine, and nitroprusside) were used almost equally for the two groups. More Group I subjects received dopamine. That is, 8 out of 19 subjects in Group I versus 4 out of 17 in Group II received dopamine. The vasoconstricting

effect of dopamine may have promoted peripheral vasoconstriction, which may have lengthened the rewarming time for Group I. This vasoconstricting effect is difficult to measure and isolate because of the variability of the individual response to the drug and the manner in which the intravenous infusion data was recorded.

Total rewarming time. There were no significant differences in the total rewarming times between the two groups ($p = .643$). The original hypothesis, that hypothermic postoperative cardiac surgery patients wearing head covers would require less total rewarming time to reach a urinary bladder temperature of 36.5°C than hypothermic postoperative cardiac surgery patients not wearing head covers, was based on a preliminary data analysis (chart review) of patients who underwent coronary artery bypass surgery one year prior to data collection. Because of incomplete recording of data on anesthesia and CTSICU flowsheets, it was difficult to determine the actual variability in the lowest induced temperatures that the patients reached in the OR. Inspection of the results of the present study demonstrated greater variability in this baseline temperature than was expected. Therefore, further analysis of the data was necessary before this investigator could draw accurate conclusions about the effects of head insulation on the sample population.

Total temperature change. There were no significant

differences (by group) in the mean total temperature change required to reach of at least 36.5°C in CTSICU ($p = .974$). When the study was proposed, it was not anticipated that there would be such a wide variance in the lowest temperature that was induced for subjects while on cardiopulmonary bypass in the OR. However, there was wide a variability of this measure within the groups. Consequently, the total change in urinary bladder temperature that was required to reach at least 36.5°C in the CTSICU was different for each subject. For example, a Group I subject required the greatest temperature increase of 11.2°C to reach 36.5°C. The subject who required the smallest change of 0.5°C was in Group II.

The level of hypothermia induced while the subjects were on cardiopulmonary bypass may be related to the techniques of the four different perfusionists at the study site. This investigator was present in the OR and the CTSICU as an observer during the entire study period for each subject. Differences were observed in the amount of cooling and the temperature level when rewarming was initiated in the OR. Considering the variability in the level of cooling between study subjects, it was determined that the rate of change in temperature would be a more appropriate measure of group difference.

Rate of change in urinary bladder temperature. There was no significant difference in the rate of temperature change

during the rewarming period. The mean rate of temperature change was slightly faster for experimental subjects. Using this measure however, the hypothesis was not supported. Group differences in total rate of change failed to reach statistical significance ($p = .447$). Moreover, head insulation only increased the rate of temperature change by 7.98 percent for the experimental group. This very small improvement in the rate of rewarming does not establish clinical significance. Based on these findings, it is doubtful that enrolling more subjects to increase the statistical power of the study would demonstrate clinical usefulness.

Heat loss from the human head can be as much as 25 to 60 percent of the total body heat loss in the intact individual (Froese & Burton, 1957). Nursing researchers demonstrated statistically and clinically significant effects of head insulation for intraoperative and postoperative general surgery patients (Biddle & Biddle, 1895; Morgester, 1987). The evidence obtained in this study demonstrated that head insulation did not have a significant effect on the rate of temperature change during the perioperative rewarming period for this particular group of coronary artery bypass graft surgery patients.

The results of this study support the findings of Howell et al. (1992) who found no significant difference ($p < .05$) in

the length of time required for subjects to reach normothermia, or in the net temperature gain using head insulation during rewarming after cardiac surgery. The major differences in the two studies are time, instrumentation, and rewarming technique. Howell et al. restricted their study to the postoperative intensive care unit (ICU) period, recording rectal temperatures on admission and every hour thereafter for 8 hours. No hypothermia blankets, ventilator cascades, or any other rewarming devices such as forced air or radiant warmers were used for rewarming in the ICU or OR. Towel or towel and paper pad head covers were placed on subjects in the experimental groups when they arrived in ICU. Subjects in the Howell et al. study had mean induced OR temperatures of 31.9°C to 32.6°C. The mean CPB duration for subjects was 56 ± 16.7 to 66.7 ± 19.6 minutes. Subjects' mean rectal temperatures on arrival to ICU ranged from 35.3 to 36 ± 0.5 °C. Howell et al. noted that 31 out of 81 of their study subjects took longer than 5 hours (300 min) to rewarm.

By comparison, the subjects in the present study were warmed in the OR with hypothermia blankets beneath them on the OR table. Aluminized polyethylene head covers were placed on experimental group subjects at start of the rewarming period in the OR. Prior to transfer from the OR, all subjects were covered with aluminized polyethylene sheets. In the CTSICU, all subjects were rewarmed with radiant warmers over the upper

half of their body surface and were covered from above the pubic area to their toes with the aluminized polyethylene sheet.

In this study, this investigator examined five points, from the beginning of the rewarming period in the OR to the end of rewarming (when subjects' urinary bladder temperatures reached 36.5°C) in the CTSICU. The mean lowest induced temperature in the OR was 25.4 to 36.1°C for both groups. The mean for Group I was $29.67 \pm 1.97^{\circ}\text{C}$ and the mean lowest induced temperature for Group II was $29.6 \pm 2.2^{\circ}\text{C}$. The mean CPB times for the subjects in this study were almost double those of Howell's et al. subjects (see Tables 3 and 4). In the present study, subjects' mean temperatures on arrival were $35.91 \pm 0.62^{\circ}\text{C}$ for Group I and 35.78 ± 0.49 for Group II. Only one subject required greater than 5 hours to rewarm (316 min), and in this particular case, it may have been related to technical difficulties experienced with the hypothermia blanket in the OR.

The overall difference in total rewarming time (between this study and Howell's et al.) may have been related to the difference in the mean duration of CPB between the subjects in the two studies (the present study subjects may have achieved better total body rewarming); or perhaps, the patients in Howell's et al. study required longer to rewarm because no external rewarming devices such as hypothermia blankets or

radiant warmers were used.

More clinically useful information was obtained in the present study because it evaluated the whole rewarming period for cardiac surgery patients from the operating room to the intensive care unit. Howell's et al. study restricted their measurements to the ICU period. In addition, this investigator monitored urinary bladder temperature which is documented to be a more accurate reflection of total body rewarming (Phillips and Skov, 1988; Kruse, 1983). Phillips and Skov claimed that at temperatures less than 36.5°C, the rectal temperature reflects peripheral and not core temperature. Rectal temperature varies with blood flow to the rectum and the presence of fecal matter. Ramsey et al. (1985) noted that the amount of temperature afterdrop post-bypass is inversely related to the adequacy of total body rewarming. In their study, there was a more significant correlation between afterdrop and UBT than afterdrop and RT. In a patient without renal disease and with adequate renal perfusion, the literature supports the UBT as the best monitor of total body rewarming during CPB and the early postbypass period (Ramsey, et al. (1985); Mravinac et al. (1989); Earp (1989)).

Challenges of clinical research. This investigator observed great variability in the individual response of study subjects to cardiopulmonary bypass and pharmacologic agents, and different surgical, perfusion, and anesthetic techniques.

This made it virtually impossible to control and identify all of the variables that could have influenced the rewarming period.

This study was based on the personal experience of the investigator as a staff nurse at the study site for a duration of 3 1/2 years, prior to the study being initiated. Unknown to this investigator, before the beginning of this study, the cardiothoracic surgeons and perfusionists had become so aware of the problems of postoperative hypothermia that they started rewarming their patients to higher temperatures on cardiopulmonary bypass in the OR. The result was a decline in the degree of postoperative hypothermia experienced by cardiac surgery patients at the study site. In addition, the presence of this investigator seemed to heighten the attention toward preventing postoperative hypothermia. In light of the improvements that were made in intraoperative rewarming techniques and all of the measures that were used by this investigator to protect subjects from potential inadvertent sources of heat loss after surgical chest closure, head insulation as an adjunct to the routine rewarming protocol for the subjects in the sample population may have been so insignificant that isolation of its effect was prohibited. Consequently, the generalizability of these findings is limited to the sample population.

Applications to nursing practice

Moderate hypothermia of brief duration is well-tolerated in most individuals. Prolonged hypothermia may present a serious clinical risk for cardiac surgery patients experiencing limitations in cardiovascular function during the immediate postoperative recovery period. It is obvious that all methods for protecting these patients from heat loss and promoting efficient rewarming are critical to maintaining these patients in a steady state. Although, head insulation did not make a significant difference in the rewarming time or the rate of change in temperature for this particular sample of coronary artery bypass graft surgery patients, covering patients' heads and all exposed body surfaces may be indicated for high risk patients. Patients undergoing cardiac surgery for a second or third time, patients with diseases that affect normal thermoregulation, patients greater than 75 years old, and patients experiencing complications such as shivering or nonsurgical blood loss may benefit from additional protection against all sources of heat loss.

Nurses can play an important role in protecting patients from inadvertent heat loss. Keeping exposed body surfaces covered and maintaining room temperatures above 70°F reduces body heat loss from exposure to cool ambient temperatures and air currents and blocking transfer of radiant body heat to the environment (Erickson & Yount, 1991). Warming of intravenous fluids (crystalloids and colloids) may be indicated to

decrease conductive heat loss for patients who require large amounts of fluid replacement. Using ventilator warming cascades for postoperative patients may minimize evaporative heat loss from respiratory passages.

Recommendations for future research

Because of the restrictions placed on this investigator at the study site, major variations in the current rewarming protocol were not possible. The aluminized polyethylene sheet was an addition to the standard protocol at the study site. This was an attempt to control for any inadvertent sources of radiant and convective heat loss during transport from the OR to the CTSICU and then, in the CTSICU to protect the lower half of the subjects' bodies. However, by adding this sheet to the protocol, the variance that might be present in the normal clinical situation may have been eliminated. Therefore, it would be helpful to examine the effect of head insulation as an adjunct to radiant warming without using the aluminized polyethylene sheet during the perioperative period. In another setting it would be desirable to repeat this perioperative study using minimal rewarming techniques, such as no hypothermia blanket in the OR and room temperature thermal blankets placed on top of patients during the postoperative period.

There may be subpopulations of cardiopulmonary bypass surgery patients (not identified in this study due to the

small sample size and exclusion criteria) who might benefit from head insulation during rewarming, such as, patients over 75 years of age or patients who are bald over greater than 50% of their scalp surface. There may also be high risk patients such as those experiencing non-surgical blood loss, patients who experienced lower temperatures on cardiopulmonary bypass, or patients with known problems with wound healing who would benefit from any measures that could be used to protect them from further inadvertent sources of heat loss.

This study could be replicated with these subpopulations in mind. If replicated, it is suggested that investigators additionally exclude patients who have previously had cardiac surgery and those who have been taking aspirin prior to surgery. Both of these subpopulations are at higher risk for nonsurgical blood loss and frequently require more room temperature intravenous fluid replacement.

Significant temperature afterdrops in urinary bladder temperature were discovered in this sample population (0 to 2.9°C). The afterdrop in the nasopharyngeal temperature was observed by this investigator to be much greater for patients without the experimental head covers. However, due to inconsistencies in monitoring of this parameter by the anesthesiologists during the perioperative period, this data was not recorded. In a future study, nasopharyngeal temperatures should be considered as possibly a better measure

of the effect of head insulation.

The afterdrop phenomenon has been documented to occur over a 60 to 90 minute period post-bypass (Biddle, 1985) and was demonstrated by the sample population. Evaporative heat loss can be substantial when large, moist body cavities are exposed, as occurs when the chest cavity is open during cardiac surgery. The time interval between discontinuation of cardiopulmonary bypass and surgical chest closure is important. During this time, none of the heat that is lost from the body is being restored by the cardiopulmonary bypass machine. In this study, the majority of time between discontinuation of cardiopulmonary bypass and arriving in the CTSICU was spent by the surgeons on surgical chest closure. This time interval for study subjects ranged from 50 to 136 minutes with a mean value of 78.36 ± 16.05 minutes. Based on the 60 to 90 minute time frame noted in the literature, much of the afterdrop would have occurred in the operating room for this sample population. Operating room nurses should examine this phenomenon and alternative measures to protect these patients from post-bypass heat loss such as warming all intravenous fluids and/or raising operating room temperatures during the rewarming period.

In this particular study, there were no statistically significant differences in the total change in urinary bladder temperatures or total rewarming times between subjects with

and without head insulation. More importantly, head insulation did not promote a clinically important increase the rate of change in temperature during the rewarming period for subjects in the experimental group. This study may have demonstrated one of the major challenges involved with clinical research, that is, in attempting to control confounding variables, you eliminate the variance that might be present in a normal clinical situation. Postoperative hypothermia can lead to serious complications for cardiac surgery patients. Nurses must continue to explore different methods to improve the efficiency of their perioperative rewarming efforts.

APPENDIX A
AUTHORIZATIONS

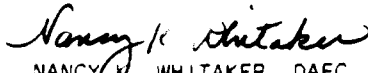
FROM: SGS

19 Aug 91

SUBJ: Clinical Investigation 91-220, "An Analysis of the Effect of Head Insulation on the Total Time Required to Rewarm Postoperative Cardiac Surgery Patients" (91HU190)

TO: Capt Michelle A. Ryerson

1. The Surgeon General's Clinical Investigation Committee has approved your proposal and has assigned file number SGO 91-220 (Atch 1). Please refer to this number in future correspondence regarding the study.
2. To assist in the proper accomplishment of this investigation, assure compliance with AFR 169-6 as it pertains to progress and final reports, proper maintenance of records, and the application of written informed consent to all study participants. Specific requirements are outlined in the attached WHMC/SGS letters, 11 Aug 89, Subj: Requirements for Conduct of Clinical Investigations (Atch 2), and 17 Dec 90, Subj: Medical Misadventures in Clinical Investigation (Atch 3).
3. Attachment 4 is an Informed Consent Document (ICD) Checklist. The primary investigator and all approved associate investigators should use this checklist when completing ICDs. Approved ICDs are maintained on file by SGS and copies can be requested by calling ext. 7141. Attached are 45 ICD sets per your request.
4. Please contact Ms Anita Benton, Clinical Investigations Gifts and Grants Coordinator, at ext. 7752, regarding the proffer of Thermadrape covers by O.R. Concepts.
5. Investigators are encouraged to obtain and use a laboratory notebook for recording their data. Notebooks may be obtained from non-medical supply, stock #7530-00-2223524. If you are unable to obtain a notebook from non-medical supply and desire to use one, contact our Admin section at ext. 7141.


NANCY K. WHITAKER, DAFC
Protocol Coordinator
Clinical Investigations

- 5 Atch
1. HQ USAF/SGPT Ltr, 16 Aug 91
 2. WHMC/SGS Ltr, 11 Aug 89
 3. WHMC SGS Ltr, 17 Dec 90
 4. ICD Checklist
 5. ICD Sets (45)

cc: SGS/Mrs Benton

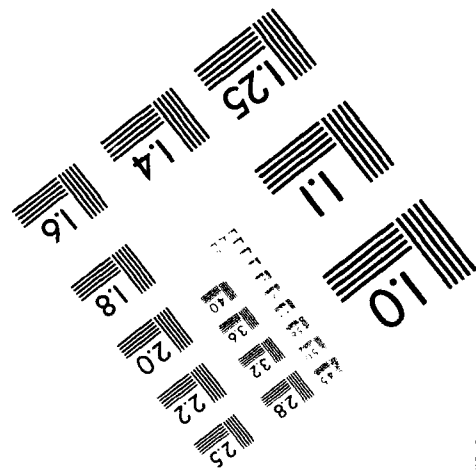
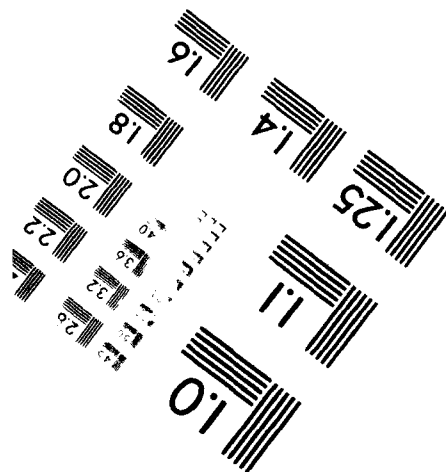
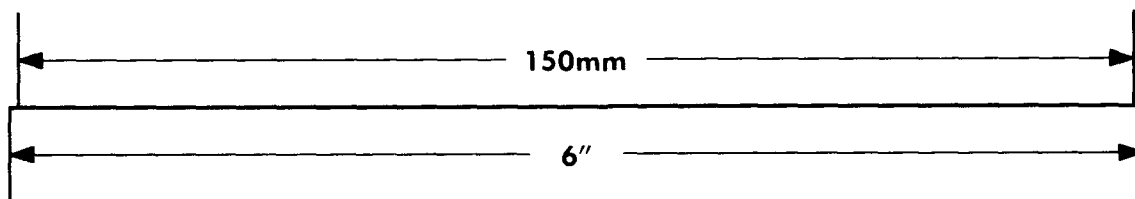
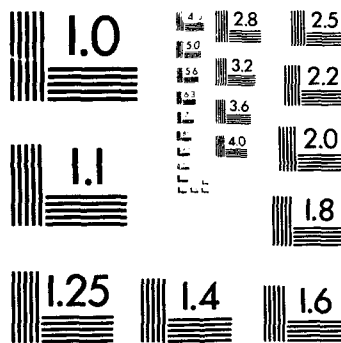
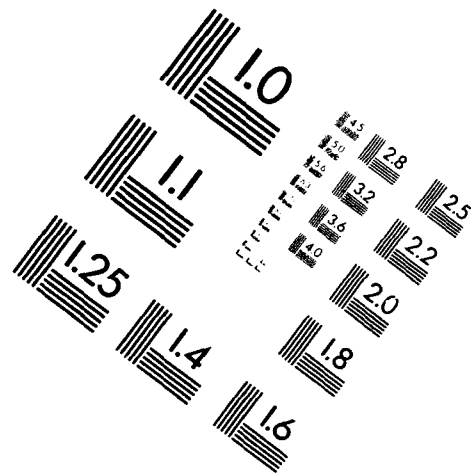
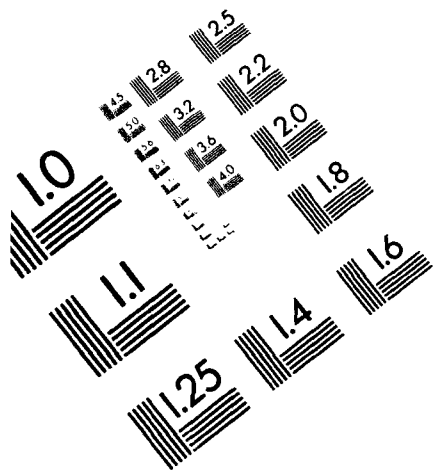
AD-294 299

EFFECT OF HEAD INSULATION ON THE TOTAL TIME REQUIRED TO
REWARM POSTOPERATIVE CARDIAC SURGERY PATIENTS(U) AIR
FORCE INST OF TECH WRIGHT-PATTERSON AFB OH
M A RYERSON MAY 92 AFIT/CI/CIA-92-044

NL



IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600



The University of Texas
Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78284-7830

Institutional Review Board
(Multiple Assurance #1403)

(512) 567-2351

July 3, 1991

Michelle A. Ryerson, Capt, USAF, NC, RN, BSN, CCRN, Graduate Student
School of Nursing
UTHSCSA

Dear Captain Ryerson:

Re: IRB Protocol #901-0020-328 An Analysis of the Effect of Head Insulation on the
Total Time Required to Rewarm Postoperative Cardiac Surgery Patients. (Wilford Hall)

This protocol was approved as resubmitted on July 3, 1991, under DHHS Regulation 46.110(3) for
EXPEDITED review: Recording of data from subjects 18 years or older using a noninvasive
procedures routinely employed in clinical practice.


This approval will be endorsed by the full Board and recorded in the minutes at the next convened
IRB meeting on July 9, 1991.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR:

- (1) report immediately to the IRB all deaths of subjects, regardless of cause;
- (2) report immediately to the IRB any severe adverse reaction or serious problem, whether anticipated or unanticipated;
- (3) report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to take part;
- (4) insure that only formally designated investigators (as approved by the IRB) enroll subjects;
- (5) submit for review and approval by the IRB all modifications to the protocol or consent form(s) prior to the implementation of the change;
- (6) submit a Progress Report for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year (a Progress Report will be sent to you in 11 months); and
- (7) notify the IRB when the study has been completed and prepare a final report.

NEXT IRB REVIEW: June 1992

(Note: Approval may need to be obtained from the appropriate hospital committee(s) prior to the implementation of this study.)


Wayne M. Pierson, Ph.D., Director, IRB

APPENDIX B
CONSENT FORM

SUBJECT CONSENT TO TAKE PART IN A STUDY OF
THE EFFECT OF HEAD INSULATION ON THE TOTAL LENGTH OF
TIME REQUIRED TO REWARM PATIENTS AFTER
CORONARY ARTERY BYPASS SURGERY

WILFORD HALL UNITED STATES AIR FORCE MEDICAL CENTER

1. I hereby volunteer to take part in a nursing research study to test a method that may be an improvement on the standard treatment currently used to reestablish normal body temperature after coronary artery bypass surgery. I was selected as a possible participant in this study because I am going to have coronary artery bypass surgery. The study period will last about eight hours or until my body temperature reaches 36.5 degrees Celsius (97.7 degrees Fahrenheit) postoperatively in the Cardio-thoracic Surgical Intensive Care Unit. Approximately 40 patients will be included in this study.
2. As a participant, I understand that I will be a subject in a study to determine whether or not head insulation influences the total length of time required for the body temperature to increase to 36.5 degrees Celsius after coronary artery bypass surgery.
3. I understand that as a participant after cardiac bypass surgery I will be randomly assigned to one of two treatment plans. By randomization, I understand that I will have an equal chance of being assigned to either treatment plan. If I am selected for the experimental treatment, I will wear a paper cap first and then a Thermadrape cap during the rewarming period in the operating room and the intensive care unit. Otherwise, I will receive the standard treatment and wear a paper cap in the operating room and no head cover during the rewarming period in the intensive care unit. During this period, my temperature, blood pressure, and other measurements will be recorded at least once every hour from standard monitors that will already be in place.
4. I understand that there are no risks to me if I agree to participate in this study and that my routine medical and nursing care will not be interrupted. My cardiac surgeon is familiar with this study and is willing to allow me to participate if I choose to do so.
5. The only possible benefit that I may receive is that my body temperature may increase more steadily toward normal

**SUBJECT CONSENT TO TAKE PART IN A STUDY OF
THE EFFECT OF HEAD INSULATION ON THE TOTAL LENGTH OF
TIME REQUIRED TO REWARM PATIENTS AFTER
CORONARY ARTERY BYPASS SURGERY**

if I am in the group of patients who wear the Thermadrape caps. However, there is no guarantee that I will receive any benefit. I will not receive money or any other compensation for participating. I understand that the only alternative treatment is for me to wear the standard head covering.

6. a. Records of my participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 USC 552a, and its implementing regulations. DD Form 2005 contains the Privacy Act Statement for the records. I understand that records of this study may be inspected by the U.S. Food and Drug Administration (FDA).

b. I understand that my entitlement to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and if I have questions about my rights or if I believe I have received a research-related injury, I may contact the Medical Center Patient Representative Chief Master Sergeant Lloyd W. Hegwood at 670-6888 and/or the principle investigator on this study, Captain Michelle Ryerson, at (512) 692-9451. I can contact the supervising professor, Dr. Don Johnson, RN, PhD, CCRN at The University of Texas Health Science Center at San Antonio School of Nursing at (512) 567-5879. The University of Texas Health Sciences Center committee that reviews research on human subjects (Institutional Review Board) will answer any of my questions about my rights as a research subject (512-567-2350).

c. I understand that any clinical or medical misadventure will be immediately brought to my attention or, if I am not competent at the time to understand the nature of the misadventure, such information will then be brought to the attention of my guardian or next of kin.

d. The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am study, my participation, and the procedures involved. I participating because I want to. Captain Ryerson has adequately answered any and all questions I have about this

**SUBJECT CONSENT TO TAKE PART IN A STUDY OF
THE EFFECT OF HEAD INSULATION ON THE TOTAL LENGTH OF
TIME REQUIRED TO REWARM PATIENTS AFTER
CORONARY ARTERY BYPASS SURGERY**

understand that Captain Ryerson will be available to answer any questions concerning procedures throughout this study. I understand that if significant new findings develop during the course of this study which may relate to my decision to continue participation, I, my guardian, or next of kin will be informed. I further understand that I may withdraw from this consent at any time and discontinue further participation in this study without prejudice to my entitlements to care. If I choose to withdraw, my condition will continue to be treated in accordance with acceptable standards of medical treatment. I also understand that the investigator of this study may terminate my participation in this study at any time if she feels this to be in my best interest.

e. A copy of this form has been given to me.

(VOLUNTEER'S SIGNATURE AND SSAN)

(DATE)

(INVESTIGATOR'S SIGNATURE AND SSN)

(DATE)

(WITNESS SIGNATURE)
(Must witness all signatures above)

(DATE)

Privacy Act of 1974 applies. DD Form 2005 filed in
Clinical/Medical Records.

Title of Study: The effect of head insulation on the total
length of time required to rewarm patients after coronary
artery bypass surgery.

SGO #: _____

Date of IRC Approval: _____

APPENDIX C
DATA COLLECTION TOOL

DATA COLLECTION TOOL - PART I
PREOPERATIVE PATIENT DEMOGRAPHICS

- 1) _____ Subject number (number in study)
_____ Subject Register Number
- 2) _____ Date (YY-MM-DD)
- 3) _____ Age (years)
- 4) _____ Sex (1 = male / 2 = female)
- 5) _____ Height (cm)
- 6) _____ Weight (kg)
- 7) _____ BSA (m³)
- 8) _____ mg/dl - Preoperative BUN
- 9) _____ mg/dl - Preoperative Creatinine
- 10) _____ Diabetic (1 = yes / 2 = no)
- 11) Other Preoperative Diagnoses:
_____ Code _____

- 12) _____ % Preoperative ejection fraction
- 13) _____ Redo CABG (1 = yes / 2 = no)
- 14) _____ Hair length (1 = bald over at least 50% of head
with short hair/ 2 = bald over at least 50% of
head with otherwise long hair/ 3 = bald over less
than 50% of head with otherwise short hair/
4 = bald over less than 50% of head with
otherwise long hair/ 5 = short/ 6 = medium /
7 = long)
- 15) _____ Preoperative oral temperature (degrees C)

DATA COLLECTION TOOL - PART II
REWARMING DEMOGRAPHICS

_____ Subject Number

- 1) _____ Group assignment (1 = experimental/ 2 = control)
- 2) _____ OR ventilator heating cascade setting (degrees C)
- 3) _____ Number of grafts required
- 4) _____ Internal mammary artery grafts (1 = yes/2 = no)
- 5) _____ Total aortic cross clamp time (minutes)
- 6) _____ Total cardiopulmonary bypass time (minutes)
- 7) _____ Attempts required to successfully wean from bypass
- 8) _____ Was patient actively recoolled after rewarming at any point? (1 = yes / 2 = no)

Anesthesia medications:

- | | | |
|---------------|-----------------|------------|
| 8) Drug _____ | Last Dose _____ | Code _____ |
| 9) _____ | (Time) _____ | _____ |
| 10) _____ | _____ | _____ |
| 11) _____ | _____ | _____ |

Paralytic Agents:

- | | |
|----------------|------------|
| 12) Drug _____ | Code _____ |
| 13) _____ | _____ |

Diuretic:

- | | |
|----------------|------------|
| 14) DRUG _____ | Code _____ |
| 15) _____ | _____ |

For questions 16 through 25, use any of the following codes that apply considering only the rewarming period:

- | | |
|----------------------------|------------------------------|
| 1 = Continuous OR | 4 = Intermittent OR |
| 2 = Continuous CTSICU | 5 = Intermittent CTSICU |
| 3 = Continuous OR & CTSICU | 6 = Intermittent OR & CTSICU |
| 7 = Never Used | |

- | | |
|--------------------------|-------------------------|
| 16) Dopamine _____ | 21) Arfonad _____ |
| 17) Dobutamine _____ | 22) Neosynephrine _____ |
| 18) Nitroprusside _____ | 23) Epinephrine _____ |
| 19) Nitroglycerine _____ | 24) Esmolol _____ |
| 20) Amrinone _____ | 25) Other IV Drug _____ |

DATA COLLECTION TOOL - PART II (cont.)

Stat medications (ie. morphine) that might affect rewarming:

26) Med _____ Time _____ Code _____
27) Med _____ Time _____ Code _____
28) Med _____ Time _____ Code _____
29) Med _____ Time _____ Code _____
30) Med _____ Time _____ Code _____

Fluid Administration From Start to End of Rewarming

OR total:

31) _____ crystals (cc)
32) _____ colloids (cc)
33) _____ total fluid warmed

ICU total:

34) _____ crystals (cc)
35) _____ colloids (cc)

Postoperative ABG Results

36) _____ ph
37) _____ PaO2
38) _____ PCO2
39) _____ Time ABG's drawn
40) _____ Postoperative BUN (mg/dl)
41) _____ Postoperative Creatinine (mg/dl)
42) _____ time creatinine drawn
43) Monitor equipment calibrated in CTSICU
 _____ (1 = yes / 2 = no)
44) _____ CTSICU ventilator heating cascade setting

Comments regarding data collection

REFERENCES

- Abbey, J., Andrews, C., Avigliano, K., Blosson, R., Bunke, B., Engberg, N., Halliburton, P., & Peterson, J. (1973). A pilot study: The control of shivering during hypothermia by a clinical nursing measure. Journal of Neurosurgical Nursing, 5, 78-88.
- Biddle, C. J., & Biddle, W. L. (1985). A plastic head cover to reduce surgical heat loss. Geriatric Nursing, 6, 39-41.
- Blair, E. (1964). Clinical hypothermia. New York: McGraw-Hill.
- Bligh, I. (1985). Regulation of body temperature in man and other animals. In A. Shetzer & R. Eberhart (Eds.), Heat transfer in medicine and biology: Analysis and applications (Vol. 1, pp. 26-23). New York: Plenum Press.
- Bullard, R. W. (1970). Problems of body heat loss in water immersion. Aerospace Medicine, 41, 1269-77.
- Burns, S. M., & Bostek, C. C. (1990). Avoiding unintentional hypothermia: Anesthesia implications. Nurse Anesthesia, 1, 128-33.
- Chiara, O., Giomarelli, P. P., Baglioli, B., Rosi, R., & Gattinoni, L. (1987). Hypermetabolic response after hypothermic cardiopulmonary bypass. Critical Care Medicine, 15, 995-99.

- Earp, J. K. (1989). Thermal gradients and shivering following open heart surgery. Dimensions of Critical Care Nursing, 8, 266-73.
- Erickson, R. S., & Yount, S. T. (1991, May). Effect of aluminized covers on body temperature in patients having abdominal surgery. Heart & Lung, 20, 255-63.
- Flacke, J. W., & Flacke, W. E. (1983). Inadvertent hypothermia: Frequent, insidious, and often serious. Seminars in Anesthesia, 2, 183-95.
- Froese, G., & Burton, A. C. (1957). Heat losses from the human head. Journal of Applied Physiology, 10-11, 235-41.
- Hertzman, A. B., & Roth, L. W. (1942). The absence of vasoconstrictor reflexes in the forehead. American Journal of Physiology, 136, 692-97.
- Holdcroft, A., & Hall, G. M. (1978). Heat loss during anaesthesia. British Journal of Anaesthesia, 50, 157-64.
- Holtzclaw, B. J. (1986). Postoperative shivering after cardiac surgery: A review. Heart & Lung, 15, 292-300.
- Howell, R. D., MacRae, L. D., Sanjines, S., Burke, J., & DeStefano, P. (1992). Effects of two types of head coverings in the rewarming of patients after coronary artery bypass graft surgery. Heart & Lung, 21, 1-5.
- Huff, B., & Dowd, A. L. (Eds.). (1989). Physician's Desk Reference (43rd ed.). NJ: Medical Economics.

- Imrie, M. M., Ward, M., & Hall, G. M. (1991). A comparison of patient rewarming devices after cardiac surgery. Anaesthesia, 46, 44-48.
- Lennon, R. L., Hosking, M. P., Conover, M. A., & Perkins, W. J. (1990). Evaluation of a forced-air system for warming hypothermic postoperative patients. Anesthesia & Analgesia, 70, 424-27.
- Lilly, R. B. (1987). Inadvertent hypothermia: A real problem. In American Society of Anesthesiologists, ASA refresher courses in anesthesiology (Vol. 15, pp. 93-107). United States: J. B. Lippincott.
- Lunn, H. F. (1969). Observations on heat gain and loss in surgery. Guy's Hospital Reports, 118, 117-27.
- Moorthy, S. S., Winn, B. A., Jallard, M. S., Edwards, K., & Smith, N. D. (1985). Monitoring urinary bladder temperature. Heart & Lung, 14, 90-93.
- Morgester, M. A. (1987). Decrease in rewarming time of hypothermic postsurgical patients through head insulation. Texas: The University of Texas Graduate School of Biomedical Sciences at San Antonio.
- Mravinac, C. M., Dracup, K., & Clochesy, J. M. (1989). Urinary bladder temperature monitoring during clinical hypothermia. Nursing Research, 38, 73-76.
- Nobak, C., & Tinker, J. (1980). Hypothermia after cardiopulmonary bypass in man: Amelioration by

nitroprusside induced vasodilation during rewarming.

Anesthesiology, 53, 277-80.

Olin, B. R., Hebel, S. K., Connell, S. I., Dombek, C. E., &

Kastrup, E. K. (Eds.). (1991). Drug facts and

comparisons (45th ed.). St Louis: J. B. Lippincott.

Osguthorpe, S. G., Tidwell, S. L., Ryan, W. J., Paull, D. L.,

& Smith, T. L. (1990). Evaluation of the patient having

cardiac surgery in the postoperative rewarming period.

Heart & Lung, 19, 570-74.

Phillips, R., & Skov, P. (1988). Rewarming and cardiac

surgery: A review. Heart & Lung, 17, 511-18.

Ralley, F. E., Ramsey, J. G., Wynands, J. E., Townsend, G. E.,

Whalley, D. G., & DelliColli, P. (1984). Effect of

heated humidified gases on temperature drop after

cardiopulmonary bypass. Anesthesia & Analgesia, 63,

1106-10.

Ramsay, J. G., Ralley, F. E., Whalley, D. G., DelliColli, P.,

& Wynands, J. E. (1985). Site of temperature monitoring

and prediction of afterdrop after open heart surgery.

Canadian Anaesthetists' Society Journal, 32, 607-12.

Rodriguez, J. L., Weissman, C., Damask, M. C., Askanazi, J.,

Hyman, A. I., & Kinney, J. M. (1983). Morphine and

postoperative rewarming in critically ill patients.

Circulation, 68, 1238-46.

Sessler, D. I., & Moayeri, A. (1990). Skin surface warming:

Heat flux and central temperature. Anesthesiology, 73, 218-24.

Shvartz, E. (1970). Effect of a cooling hood on physiological responses to work in a hot environment. Journal of Applied Physiology, 29, 36-39.

Soukup, M. (1988). Thermal Regulation. In M. R. Kinney, D. R. Packa, & S. B. Dunbar (Eds.), AACN's clinical reference for critical care nursing (2nd ed.). New York: McGraw-Hill.

Vaughan, M. S., Vaughan, R. W., & Cork, R. C. (1980). Radiation versus conduction for postop rewarming of adults. Anesthesiology, 53, S195.

Vaughan, M. S., Vaughan, R. W., & Cork, R. C. (1981). Postoperative hypothermia in adults: Relationship between age, anesthesia, and shivering. Anesthesia & Analgesia, 60, 746-51.

VITA

Michelle Ann Ryerson, daughter of John P. and Joyce A. Lawlor, was born March 6, 1959 in Geneva, New York. She received an Associate in Applied Science degree in Nursing in 1979 from The Community College of the Finger Lakes in Canandaigua, New York. She obtained a Bachelor of Science degree with a nursing major when she graduated Cum Laude from Nazareth College of Rochester, Rochester, New York in 1982.

She was first commissioned into the United States Air Force Nurse Corps on April 28, 1982. Michelle's first assignment was the intensive care unit at Malcolm Grow Air Force Base, Andrews Air Force Base, Maryland. During her second tour, in 1984, she was assigned to the intensive care unit, United States Air Force Regional Medical Center, Clark Air Base, Republic of the Philippines. In 1987, she was reassigned to Wilford Hall Medical Center, San Antonio, Texas. At Wilford Hall, Michelle was an Assistant Charge Nurse in the Cardiothoracic Surgical and Surgical Intensive Care units. Michelle is a member of the American Association of Critical Care Nurses and maintains active involvement through the San Antonio chapter. She achieved Certification in Critical Care Nursing from the American Association of Critical Care Nurses in 1991.

Michelle was selected and funded through the Air Force Institute of Technology to pursue a Master's Degree in Critical Care Nursing. She enrolled at the University of Texas Graduate School of Biomedical Sciences at San Antonio in August of 1990.

She received The University of Texas Health Science Center at San Antonio School of Nursing Scholarship for outstanding nursing clinical performance and recognized potential for contributions to the profession of nursing and a Thesis Scholarship from Sigma Theta Tau, Delta Alpha Chapter on August 26, 1991. She was inducted into the Delta Alpha Chapter of Sigma Theta Tau International Honor Society of Nursing on December 12, 1991.